FOSTERING THE U.S. COMPETITIVE EDGE: EXAMINING THE EFFECT OF FEDERAL POLICIES ON COMPETITION, INNOVATION, AND JOB GROWTH

HEARING

BEFORE THE

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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CONTENTS

Hearing Date

Witness List	Page 2					
Hearing Charter	3					
Opening Statements						
Statement by Representative Benjamin Quayle, Chairman, Subcommittee on Technology and Innovation, Committee on Science, Space, and Technology, U.S. House of Representatives Written Statement Statement by Representative Donna Edwards, Ranking Minority Member,	8 9					
Subcommittee on Technology and Innovation, Committee on Science, Space, and Technology, U.S. House of Representatives Written Statement	10 11					
Witnesses:						
Mr. Ron Cohen, President and CEO, Acorda Therapeutics Oral Statement Written Statement	13 15					
Mr. Mick Truitt, Vice President, Ludlum Measurements, Inc. Oral Statement Written Statement Mr. Thomas M. Brandt, Jr., Senior Vice President and CFO, Telecommuni-	28 31					
cations Systems, Inc. Oral Statement Written Statement Mr. Richard Bendis, Interim CEO, Biohealth Innovation, Inc., and President and CEO, Innovation America	47 50					
Oral Statement Written Statement Discussion	63 66 71					
Appendix 1: Answers to Post-Hearing Questions						
Mr. Ron Cohen, President and CEO, Acorda Therapeutics	83 89 93					
Mr. Richard Bendis, Interim CEO, Biohealth Innovation, Inc., and President and CEO, Innovation America	95					
Appendix 2: Additional Material for the Record						
TechAmerica: Technology Roadmap for America	102					

FOSTERING THE U.S. COMPETITIVE EDGE: EXAMINING THE EFFECT OF FEDERAL POLICIES ON COMPETITION, INNOVATION, AND JOB GROWTH

TUESDAY, MARCH 27, 2012

House of Representatives,
Subcommittee on Technology and Innovation,
Committee on Science, Space, and Technology,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:15 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Benjamin Quayle [Chairman of the Subcommittee] presiding.

RALPH M. HALL, TEXAS CHAIRMAN EDDJE BERNICE JOHNSON, TEXAS RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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Subcommittee on Technology and Innovation Hearing

Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth

Tuesday, March 27, 2012 10:00 a.m. – 12:00 p.m. 2318 Rayburn House Office Building

Witnesses

Dr. Ron Cohen, President and CEO, Acorda Therapeutics.

Mr. Mick Truitt, Vice President, Ludlum Measurements, Inc.

Mr. Thomas M. Brandt, Jr., Sr. Vice President and CFO, TeleCommunications Systems, Inc.

Mr. Richard Bendis, Interim CEO, BioHealth Innovation; President and CEO, Innovation America.

U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

HEARING CHARTER

Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth

Tuesday, March 27, 2012 10:00 a.m. – 12:00 p.m. 2318 Rayburn House Office Building

I. Purpose

On Tuesday, March 27, 2012, the Committee on Science, Space, and Technology Subcommittee on Technology and Innovation will convene a hearing to better understand how Federal policies and regulations affect competition, innovation and job growth, and to solicit input from leaders of innovative companies on ways to improve Federal economic and regulatory policy.

II. Witnesses

Dr. Ron Cohen, President and CEO, Acorda Therapeutics.

Mr. Mick Truitt, Vice President, Ludlum Measurements, Inc.

Mr. Thomas M. Brandt, Jr., Sr. Vice President and CFO, TeleCommunications Systems, Inc.

Mr. Richard Bendis, Interim CEO, BioHealth Innovation; President and CEO, Innovation America.

III. Background

Competitiveness and innovation are crucial to ensuring economic growth and job creation in a global economy. Historically, the United States proved to be an excellent place from which to launch a new business, cultivating domestic entrepreneurship and attracting talent from around the world. The U.S. is home to a multitude of innovative companies in various high-growth sectors. U.S.-headquartered companies make up a disproportionate share on the lists of global companies by market capitalization, such as the Financial Times Global 500¹. The U.S. is also home to 14 of the top 20 universities, according to the Times Higher Education World University Rankings.²

¹ http://media.ft.com/cms/33558890-98d4-11e0-bd66-00144feab49a.pdf

² http://www.timeshighereducation.co.uk/world-university-rankings/2011-2012/top-400.html

The United States continues to have the largest economy in the world. According to the Organization for Economic Co-operation and Development (OECD), the U.S.'s 2010 Gross Domestic Product (GDP) was nearly 43 percent higher than China's, the second country on the list, in terms of purchasing power parity³.

However, recent trends suggest that other countries are catching up in terms of economic growth and competitiveness. In fact, a study by the Information Technology and Innovation Foundation, a non-partisan research and educational institute, ranks the U.S. sixth out of 40 countries in overall innovation-based competitiveness.⁴

According to The Conference Board, a global, independent business membership and research organization, U.S. GDP is estimated to grow at an average annual percentage rate of 2.3 in the years 2012-2016⁵, below the post-World War II average of 3.25 percent⁶. Unemployment currently sits at 8.3 percent, according to the February 2011 Bureau of Labor Statistics Report. Some economists predict that China's GDP will surpass that of the United States in terms of purchasing power parity in 2016 and in market exchange rate value by 2018.

Policymakers from different countries recognized the success of innovative companies in the United States (including small, medium, and large companies) and implemented policies to cultivate innovation-led growth in their own countries. These policies cover a wide spectrum including tax, research, regulation, human capital, and trade policies, among many others.

Today's hearing is intended to examine how Federal policies and regulations affect competitiveness, innovation, and job growth. Witnesses will discuss the advantages and disadvantages of current Federal policies, and will make recommendations on how changes to Federal policies can improve the country's competitive profile to ensure that the U.S. remains the preeminent country in which to launch or expand a business.

IV. Federal Policy and Competitiveness

In a developed economy such as that of the United States, private sector innovation is critical to economic growth. Studies have demonstrated that innovation leads to mid-term and long-term employment and income growth. Indeed, according to the Information Technology Industry Council, an association of information and communications technology firms, innovation has

³ http://stats.oecd.org/index.aspx?queryid=556

⁴ R. Atkinson and S. Andes, "The Atlantic Century: Benchmarking EU & U.S. Competitiveness." Information Technology and Innovation Foundation, 2009.

 $^{^{5} \,} http://www.conference-board.org/data/globaloutlook.cfm$

⁶ http://www.tradingeconomics.com/united-states/gdp-growth-annual

⁷ http://www.bls.gov/news.release/pdf/empsit.pdf

⁸ http://www.economist.com/blogs/dailychart/2010/12/save_date

⁹ R. Atkinson, D. Castro, S. Andes, S. Ezell, D. Hackler, and R. Bennett, "Innovation Policy on a Budget: Driving Innovation in a Time of Fiscal Constraint." Information Technology and Innovation Foundation. September 2010

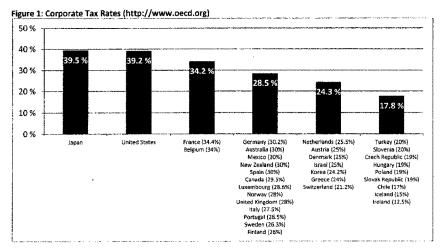
been responsible for approximately 80 percent of the growth in the U.S. economy since World War II. 10

Other countries recognize the importance of promoting innovation-led growth and have adopted policies intended to increase foreign direct investment and domestic development and production.

Today's hearing will examine the effects of the following policies (among others) on competitiveness and innovation.

Corporate Tax Policy

The U.S. currently has the second highest marginal corporate tax rate in the OECD at 35 percent (39.2 percent including state and local taxes). Many OECD countries have lowered corporate tax rates over the last 20 years to improve their competitiveness. Indeed, if Japan changes its corporate tax rate on April 1 as expected, the U.S. will have the highest marginal corporate tax rate in the OECD (see figure 1). Even after accounting for credits and deductions, the U.S. effective tax rate is more than 5 percentage points higher than the effective tax rate for the rest of the OECD. 12



Other tax policies that affect competitiveness and innovation include the tax treatment and filing status of companies, as well as different countries' policies on taxation of foreign earnings for exporters.

12 http://businessroundtable.org/uploads/studies-reports/downloads/Effective_Tax_Rate_Study.pdf

¹⁰ Information Technology Industry Council (www.itic.org)

¹¹ http://www.oecd.org/document/60/0,3746,en_2649_34533_1942460_1_1_1_1_0.0.html#C_CorporateCaptial

Regulation

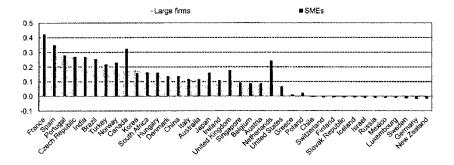
Federal regulations affect the cost of doing business for companies and therefore affect competitiveness. Regulations can have different effects on different sized businesses. A 2008 study commissioned by the Small Business Administration determined that small businesses faced an annual regulatory cost of \$10,585 per employee, which was 36 percent higher than the regulatory costs facing large firms. ¹³ The Committee will examine the effects of regulatory policy on U.S. competitiveness for small, medium, and large firms.

Research

R&D Tax Credit

The U.S. was the first industrialized country to adopt a comprehensive research and development tax credit in 1981. This credit provided incentives to businesses for conducting research which might lead to potential new products and services, even though the benefits of this research could accrue beyond the company conducting the research. Many countries followed suit and now offer more robust credits to fund research activities at private companies. France has enacted an R&D tax credit six times more generous than that of the U.S.'s (see figure 2) ¹⁴.

Figure 2: R&D Tax Credit (OECD Science, Technology and Industry Scoreboard 2009 - OECD © 2009)



Industry/Federal Funding for Research

According to Batelle, a major research and development organization focused on scientific discovery and application, U.S. funding of research and development totaled \$427.2 billion in 2011, of which \$270 billion came from industry, \$128 billion from the Federal Government, and \$30 billion from academic and other sources. ¹⁵ The Committee will examine prioritization of

¹³ http://archive.sba.gov/advo/research/rs371tot.pdf

¹⁴ www.oecdilibrary.org/content/ book/sti_scoreboard-2009-en

^{15 2012} Global R&D Funding Forecast

Federal funding for basic and applied research programs within the context of the challenging budget environment.

Human Capital

Innovative companies in knowledge-based economies depend on a talented workforce to develop new products and services or to improve existing products and services. Science, Technology, Engineering, and Math (STEM) education and immigration policies have an effect on competitiveness and innovation and the Committee will seek input from witnesses on these issues.

Trade

Innovative companies that export products and services depend on access to foreign markets. Trade policies affect the cost of doing business for companies in global markets. The Committee will examine Federal trade policies, including existing and potential trade agreements.

V. Questions for Witnesses

Witnesses have been asked to: provide recommendations on policies the Congress should enact to improve American competitiveness and to promote innovation; describe whether current Federal policies inhibit their companies' ability to innovate and, if so, recommend steps that Federal policy-makers can take to alleviate this burden; describe how Federal policy or regulatory uncertainty affects their companies' ability to make business decisions; and describe how individual country's economic policies influence their companies' decisions to establish or expand business operations.

Chairman QUAYLE. The Subcommittee on Technology and Innovation will come to order. Good morning. Welcome to today's hearing entitled "Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation and Job Growth," which is being held to examine the effect of federal policies on U.S. competitiveness and innovation. In front of you are packets containing the written testimony, biographies and Truth in Testimony disclosures for today's witnesses. I now recognize myself for five minutes for an opening statement.

Today's discussion is the fourth in a series focused on advancing U.S. innovation in a constrained budget environment, following hearings on cloud computing, startup companies, and principles of

effective standards development.

At the Committee on Science, Space, and Technology, we are fortunate that we have the opportunity to influence the Federal Government's investments in basic research, which can result in gamechanging innovations 10, 20, even 30 years down the line. We also influence science education policy, helping to ensure our Nation's future workforce remains competitive in the global economy.

While these policy areas are vital to U.S. competitiveness and innovation, there are several other policy areas that affect our coun-

try's competitive standing.

These areas include taxes, regulation, trade, protection of intellectual property, and human capital, among many others. According to House Rule X, Clause 2(c): "Each standing committee shall review and study on a continuing basis the impact or probable impact of tax policies affecting subjects within its jurisdiction."

As part of carrying out our oversight responsibilities, the Committee reviews laws, programs, and government activities that affect the country's competitiveness and innovation. Therefore, as we hear a range of policy recommendations from our witnesses today, it is imperative that we understand how these many issues affect

our Nation's economic competitive position.

As of April 1, the United States will have the dubious honor of having the highest marginal corporate income tax in the industrialized world. This tax rate harms competitiveness by taking money away from companies that could be better used to conduct research, develop new innovations and create jobs. And it encourages companies to look for more favorable business environments abroad.

Policy uncertainty can also make private sector business and investment decisions more difficult. For instance, the Research and Development Tax Credit has expired 14 times since it was first authorized under President Reagan in 1981. While the Congress has repeatedly extended this credit, it generally has not done so until the end of each year, adding a layer of uncertainty to company investment decisions.

Excessive regulations and red tape increase the cost of doing business and create uncertainty for private sector companies. A study commissioned by the Small Business Administration in 2008 calculated that small businesses faced annual regulatory costs of \$10,585 per employee. In the first three years of the Obama Administration, the Federal Government imposed 106 new major regulations with annual costs of more than \$46 billion. By piling on

new hoops for employers to jump through, we are simply increasing

costs that are passed on to consumers.

Finally, our country's deficit is projected to exceed \$1 trillion for the fourth straight year, and our gross national debt exceeds \$15 trillion. This fiscal path is unsustainable. It is bad for business, and it is just plain wrong. Clearly, we must do better. As policymakers, we need to foster an environment that allows U.S.-based innovators to compete and to flourish. We should enact policies that ensure this country remains the best place to launch or expand a business.

Today, we will be examining how federal policies and regulations affect competition, innovation and job growth and we will be hearing recommendations from leaders of innovative companies and technology transfer organizations on ways to improve federal eco-

nomic and regulatory policy.

We thank our witnesses for being here today, and we look for-

ward to your testimony.

At this time, I am going to submit for the record Tech America's Technology Roadmap for America. Without objection, so ordered. [The prepared statement of Mr. Quayle follows:]

PREPARED STATEMENT OF SUBCOMMITTEE CHAIRMAN BENJAMIN QUAYLE

Good morning, I'd like to welcome everyone to today's hearing, which is being held to examine the effect of federal policies on U.S. competitiveness and innovation.

Today's discussion is the fourth in a series focused on advancing U.S. innovation in a constrained budget environment, following hearings on cloud computing, startup companies, and principles of effective standards development.

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Finally, our country's deficit is projected to exceed \$1 trillion for the fourth straight year, and our gross national debt exceeds \$15 trillion. This fiscal path is unsustainable. It's bad for business, and it is wrong.

Clearly, we must do better.

As policy makers, we need to foster an environment that allows U.S.-based innovators to compete and to flourish. We should enact policies that ensure this

country remains the best place to launch or expand a business.

Today, we will be examining how federal policies and regulations affect competition, innovation and job growth and we will be hearing recommendations from leaders of innovative companies and technology transfer organizations on ways to improve federal economic and regulatory policy.

We thank our witnesses for being here today and we look forward to your testi-

Chairman QUAYLE. I now recognize the gentlelady from Maryland, Ms. Edwards, the Ranking Member, for her opening statement.

Ms. EDWARDS. Thank you very much, Mr. Chairman, and thank you for calling this hearing on competition, innovation, and job growth. This hearing is an important follow-up to one that we held back in November on small business creation.

I am pleased that we are taking an in-depth look at these issues as we seek to identify the best federal policies for fostering innovation and job growth and preserving our competitive edge in the global economy. And I thank the witnesses for being here today.

Without a doubt, regulatory, tax, immigration, and economic policies have an unquestionable impact on innovation and competitiveness. And there are important steps that we can and should take in Congress to address these issues, including policies that I have long advocated, such as increasing and making permanent the research and development tax credit and providing incentives for businesses to co-locate their research and development and manufacturing activities here in the United States.

In addition, I am strongly supportive of efforts by policymakers and business leaders in my home State of Maryland to enact a measure to make more companies eligible for the State's biotech investment tax credit and to streamline the application process, aid-

ing countless small- and medium-sized businesses.

Locally, in Montgomery County, which I represent along with Prince George's County, the biotech investment tax credit, the first such program at the local level anywhere in the country and modeled after the State's program, has helped facilitate nearly \$6 million in local investment for a number of local biotech companies. These are very promising programs that ought to be replicated elsewhere.

However, for our purposes of today's hearing and despite my advocacy for some issues that do not fall under this Committee's jurisdiction, I think it is most worthwhile for us to focus on the areas and programs within our committee's jurisdiction, and these can have an important impact on innovation and competitiveness.

We have legislative authority over many programs throughout the Federal Government that are seeking to partner with the private sector, State and local governments, academia, and others to promote innovation- and technology-based economic development. For example, in the America COMPETES Reauthorization Act of 2010, we authorized the Office of Innovation and Entrepreneurship and the regional innovation strategies program at the Economic

Development Administration. These programs are up for reauthorization next year. I think it would be a valuable use of our time to check in on the progress of these programs and to hear from our witnesses today about how they might be improved, enhanced, or expanded.

The truth is that there is much that can be done in the area of regional innovation beyond the critical aspect of creating linkages between and amongst the various stakeholders in a region. There are interesting ideas involving shared facilities, collaborative research and development, and commercialization that we ought to be exploring in an effort to enhance regional innovation and economic development. That is why I am particularly pleased that Mr. Bendis is joining us today as a witness. I am very interested in the BioHealth Innovation initiative, and I am very supportive of efforts to formalize and accelerate development of a biotechnology cluster in the Central Maryland region. We have extraordinary and unparalleled biotech assets in Central Maryland that can be and ought to be leveraged to make the region a truly global force in biotechnology.

In addition to EDA's efforts with respect to regional innovation and economic development, there are also some very relevant, White House-led policies under way that deserve some examination and review. These include the President's Public-Private Start-Up America initiative and his recent efforts to enhance and improve

technology transfer from our federal labs.

We have jurisdiction in this committee over these programs and policies, and we should make the effort to evaluate their effectiveness to determine if there are steps that we could take by legisla-

tively strengthening or improving them.

I think it would also be worthwhile for us to take a serious look at what is going on with our international competitors. Other countries, including Germany, Singapore, and China, are pouring significant amounts of money into programs to spur innovation and are trying out some interesting new models. We should seek to better understand these models, the lessons learned and the best practices, and explore the possibility of piloting some of them here in the United States.

I look forward to hearing from our witnesses today and hope we have an opportunity to touch on some of these important issues, and I yield the balance of my time.

[The prepared statement of Ms. Edwards follows:]

PREPARED STATEMENT OF RANKING MINORITY MEMBER DONNA EDWARDS

Mr. Chairman, thank you for calling this hearing on competition, innovation, and job growth. This hearing is an important follow-up to the hearing we held back in November on small business creation. I'm glad that we are taking an in-depth look at these issues as we seek to identify the best federal policies for fostering innovation and job growth and preserving our competitive edge in the global economy. And thank you to the witnesses for being here.

Without a doubt, regulatory, tax, immigration, and economic policies have an impact on innovation and competitiveness. And there are important steps that we can—and should—take in Congress to address these issues, including policies that I've long advocated such as increasing and making permanent the R & D tax credit and providing incentives for businesses to co-locate their research and development and manufacturing activities here in the United States.

In addition, I'm strongly supportive of efforts by policymakers and business leaders in my home state of Maryland to enact a measure to make more companies eligible for the State's biotech investment tax credit and streamline the application process, aiding countless small- and medium-sized businesses. Locally, in Montgomery County, which I represent along with Prince George's County, the biotech investment tax credit—the first such program at the local level anywhere in the country and modeled after the State's program—has helped facilitate nearly \$6 million in local investment for a number of local biotech companies. These are very promising programs that ought to be replicated elsewhere.

However, for our purposes today, I think it is most worthwhile for us to focus on those areas and programs within our Committee's jurisdiction that have an impact on innovation and competitiveness. We have legislative authority over many programs throughout the Federal Government that are seeking to partner with the private sector, State and local governments, academia, and others to promote innovation- and technology-based economic development. For example, in the *Amer*ica COMPETES Reauthorization Act of 2010, we authorized the Office of Innovation and Entrepreneurship and the regional innovation strategies program at the Eco-

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I think it would also be worthwhile for us to take a serious look at what's going on with our international competitors. Other countries, including Germany, Singapore, and China, are pouring significant amounts of money into programs to spur innovation and are trying out some interesting new models. We should seek to better understand these new models, the lessons learned and the best practices, and explore the possibility of piloting some of them in the United States.

I look forward to hearing from our witnesses today, and hope that we will have

an opportunity to touch on some of these important issues. I yield back the balance

Chairman QUAYLE. Thank you, Ms. Edwards. If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

At this time, I would like to introduce our witnesses, and then

we will proceed to hear from each of them in order.

Our first witness is Dr. Ron Cohen, President and CEO of Acorda Therapeutics. In his current position, he oversees a public biotechnology company aimed at bettering the lives of those afflicted with a variety of neurological conditions. Next we will hear from Mr. Mick Truitt, Vice President of Ludlum Measurements, Inc. In this capacity, Mr. Truitt has dealt with the extensive growth in the international markets. Our third witness is Mr. Thomas Brandt, Jr., who is the Senior Vice President and Chief Financial Officer of TeleCommunications Systems, Inc., a wireless technology solutions provider. Mr. Brandt is also here on behalf of TechAmerica,

an association of diverse U.S. technology companies. Our fourth witness is Mr. Richard A. Bendis, the Interim CEO of BioHealth Innovation, Inc., and President and CEO of Innovation America. These current roles allow Mr. Bendis to lead two innovation intermediaries which help bring together the range of organizations and knowledge necessary to spur innovation. Thanks again to all of our witnesses for being here this morning.

As our witnesses should know, spoken testimony is limited to five minutes each. After all witnesses have spoken, Members of the Committee will have five minutes each to ask questions. I now recognize our first witness, Dr. Ron Cohen, for five minutes.

STATEMENT OF DR. RON COHEN,

PRESIDENT AND CEO, ACORDA THERAPEUTICS

Dr. COHEN. Chairman Quayle and Ranking Member Edwards, Members of the Committee, it is my privilege to be here today to discuss ways to foster biomedical innovation in the United States.

My name is Ron Cohen and I am the President, CEO, and founder of Acorda Therapeutics, Inc. I have over 25 years of experience in the biotechnology industry, and I am appearing before this Committee on behalf of the Biotechnology Industry Organization, or BIO, where I serve as Chairman of the Emerging Companies section of the Board.

Acorda is a small biotechnology company located in Hawthorne, New York. I founded the company in 1995 with one mission, to develop therapies that could restore neurological function to people with multiple sclerosis, spinal cord injuries, and other conditions that affect the nervous system.

In 2010, after 15 years of effort, we obtained FDA approval for Ampyra, a drug that improves walking in people with MS, a significant improvement in a basic function that affects the lives of MS patients.

Our company went public in 2006, and today we employ over 330 people who are working on a pipeline of innovative medicines that could be transformative in the lives of patients afflicted with these terrible diseases.

America has developed more cures and breakthroughs than any other country. However, this position will not be sustained without a concerted policy focused on supporting and incentivizing the next frontiers of biomedical discoveries, treatments, and cures. Unfortunately, investors are now decreasing their funding in early-stage companies, such as ours, developing potential medical breakthroughs. Even as we are decreasing our investment in early-stage biotechnology in the United States, we are facing unprecedented competition from around the globe to be the leader in biomedical research. In 2008, China pledged to invest \$12 billion in drug development, and in 2011, the Chinese government named biotechnology as one of seven industries that will receive \$1.7 trillion in government funding over the next five years. The competitive gap is getting smaller.

The U.S. biotechnology industry is poised to be a major driver in an innovation-driven economy, and we offer real solutions to our most pressing healthcare needs: curing diseases, reducing costs, increasing quality, and ensuring that people enjoy not only longer lives but better and more productive lives. In fact, today the Nation's biotechnology industry employs 1.42 million people and supports an additional 6.6 million jobs.

In order to truly realize these potential benefits, we must have a policy environment that fosters innovation. My written testimony discusses five policy areas that would better enable us to do this. For my oral testimony today, I want to focus on two areas, tax pol-

icy and regulatory environment.

In the past, Congress has provided tax incentives that mitigate risk and enhance the returns of innovative development projects like those found in our companies. The growth of the industry in the early 1980s was due in part to the ability of growing companies to pass through various tax incentives, including credits and losses, to their investors. This sponsored and promoted a great deal of investment in the industry. Allowing certain tax incentives stemming from R&D to flow through life science projects to their investors would result in immediate tax benefits to investors and encourage further investment.

On the regulatory front, we need to have a strong successful FDA and a transparent FDA. It is imperative that the FDA have the resources that it needs. In 1992, Congress, industry, and the FDA created the PDUFA, or the *Prescription Drug User Fee Act*. This ensured that the FDA would have the wherewithal to hire the reviewers it needed, to expedite the drug development process. And this year, the fifth reauthorization of that very successful program is up for renewal, PDUFA V. This PDUFA V legislation will further streamline the activities of the FDA, and I encourage Congress to pass that.

In addition, Congressmen Stearns' and Townes' Faster Access to Specialized Therapies Act, or the FAST bill, would create a robust, accelerated approval pathway that would enable the safe and expeditious development of the next generations of modern medicines. I encourage passage of the FAST Act and the benefits that will accrue from it.

Thank you very much for the opportunity to speak to you today. [The prepared statement of Dr. Cohen follows:]

PREPARED STATEMENT OF DR. ROY COHEN



TESTIMONY OF RON COHEN, M.D.

PRESIDENT & CHIEF EXECUTIVE OFFICER, ACORDA THERAPEUTICS

ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION HEARING ON:

"FOSTERING THE COMPETITIVE EDGE: EXAMINING THE EFFECT OF FEDERAL POLICIES ON COMPETITION, INNOVATION, AND JOB GROWTH"

March 27, 2012

Chairman Quayle and Ranking Member Edwards, Members of the Committee, it is my privilege to provide testimony today on the crucial issue of ensuring we foster biomedical innovation in the United States. My name is Ron Cohen and I am the President, CEO, and founder of Acorda Therapeutics, Inc. Prior to founding Acorda, I was a principal in Advanced Tissue Sciences, Inc., a biotechnology company engaged in the growth of human organ tissues for transplantation. I have over 25 years of experience in the biotechnology industry and currently serve as a member of the Columbia-Presbyterian Health Sciences Advisory Council. I am a recipient of the Ernst & Young Entrepreneur of the Year Award for the New York Metropolitan Region and am an inductee of the National Spinal Cord Injury Association's "Spinal Cord Injury Hall of Fame." I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO), where I serve as Chairman of the Emerging Companies Section Governing Board. BIO represents more than 1,100 companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

Acorda is a small biotechnology company located in Hawthorne, New York, I founded the company in 1995 with one mission—to develop therapies that could restore neurological function and improve the lives of people with multiple sclerosis (MS), spinal cord injury (SCI), and other disorders of the nervous system. We launched our first FDA-approved medication,

Zanaflex Capsules, in 2005; Zanaflex is a drug that helps with the management of spasticity. In 2010 we obtained FDA approval for Ampyra, a drug that improves walking in people with MS: the majority of patients afflicted with this disease experience impairment in their ability to walk. In addition to Ampyra and Zanaflex, we are working on four treatments that we hope will protect nerves in the spinal cord or brain from the consequences of traumatic injury or stroke, regenerate neural connections in existing injuries, and address damage to or loss of myelin (the insulating layer of cells that surround nerve fibers).

Our company went public in 2006 and today we have 330 employees who are working on our pipeline of innovative medicines that could be transformative in the lives of patients afflicted with neurological diseases. Although the company has matured and many of our employees are based at our headquarters in Hawthorne, NY, we have remained true to our origins as a collaborative enterprise – both within the company and with external partners in academia and industry, with whom we share a sense of mission. This unusually high level of teamwork has contributed substantially to our ability to innovate successfully, from product identification to preclinical, clinical, and commercial development.

I am here today to talk about the state of the biotechnology industry in the United States and to discuss polices that have been enacted or are currently being considered by Congress that would ensure we have a robust biotech industry in the U.S. for the foreseeable future.

THE UNITED STATES BIOTECHNOLOGY INDUSTRY: IMPORTANCE OF DEVELOPING POLICIES THAT FOSTER INNOVATION

It is imperative that we have policies that encourage research and development of the next generation of treatments and cures. America has developed more cures and breakthrough medicines than any other country and is home to over 2,500 biotech companies. However, this position cannot be sustained without a concerted policy focus on supporting and incentivizing the next frontier of biomedical discoveries, treatments, and cures. Recently there have been a few headlines touting increased investment in the biomedical field. Unfortunately, these headlines oversimplify the actual state of affairs. The National Venture Capital Association (NVCA) recently released their fourth quarter 2011 numbers for venture financing of

biotechnology in the U.S. While the numbers showed an overall 18% increase in investment from 2010 to 2011, this is misleading with regard to the situation that most small, innovative biotechnology companies are facing. The 2011 investment in biotechnology is actually 12% lower than the peak we saw in 2007, and the total number of venture financing deals was down 8% since 2010. Most importantly, especially to small innovative companies, the number of venture-funded early-stage companies fell by 19%. The number of investments moving away from early-stage innovative projects is an alarming trend that has been growing over the past few years – in fact, the number of first-time financings for life sciences companies is at its lowest level since 1996.

Over the past year we have seen several long-time investment funds announce they will no tonger be investing in the medical science sectors. An October 2011 survey conducted by the NVCA and MedIC showed that 40% of venture capitalists expect to decrease investment in biopharma over the next three years, three times as many as the number who expect to increase. This same survey showed that 61% cited regulatory challenges at the FDA as the main reason for reducing investments. This is not entirely surprising given that the time and costs to develop a novel drug have continued to increase over the past decade. In fact, today, it requires an average of 10 to 15 years and \$800 million to over \$1 billion to develop a new drug, and that cost is continuing to increase at a disturbing rate. Sec. In part this increase in cost can be attributed to the increased complexity of regulatory requirements. For example, between 1999 and 2005 the average length of clinical trials grew by 70%. The combination of these increased costs,

NVCA/PWC MoneyTree Report: Q4 2011, Data provided by Thomson Reuters.

² "Venture Capital increases in 2011, but..." Inside BIO Industry Analysis, 24 January 2012. http://www.biotechnow.org/business-and-investments/inside-bio-ia/2012/01/vc2011

NVCA/PWC MoneyTree Report: Q4 2011, Data provided by Thomson Reuters.

⁴ NVCA/MedIC Survey. Vital Signs. October 2011.

^{5 &}quot;Returns to R&D on New Drug Introductions in the 1980s," Journal of Health Feonomies 13, no. 4 (1994): 383-466

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&</sup>lt;sup>6</sup> H.G. Grabowski, J. Vernon, and J.A. DiMasi, 'Returns on Research and Development for 1990s New Drug baroductions,' Pharmacrocommunics 26, supp. 3 (2002): 11–29

Introductions," Pharmacocconomics 20, supp. 3 (2002): 11–29

3. Dimasi and H Grabowski I "The Cost of Biopharmaceutical R&D: is Biotech Different?" Managerial and Decision Economics no 28 (2007): 469–79

³ Manos, Bernard, "Lessons from 60 years of pharmaceutical innovation," Nature Reviews Drug Discovery 8, 959-968 (December 2009).

^{*} Fulls Center for the Study of Drug Development, 2008, "Growing Protocol Design Complexity Stresses Investigators, Volunteers." Impact Report, 10.1.

regulatory uncertainty, and lack of fiscal incentives is causing investors to move their funds to lower risk propositions and/or overseas.

We are facing unprecedented competition from around the globe to be the leader in biomedical research. In 2008, China pledged to invest \$12 billion in drug development, to and in 2011, the Chinese government named biotechnology as one of seven industries that will receive \$1.7 trillion in government funding over the next five years. 11 The European Union's Innovative Medicines Initiative is pumping \$2.65 billion into Europe's biopharma industry¹² and India's Bioconnect initiative has funded over 200 new biopharma projects.¹³ While America has developed more cures and breakthrough medicines than any other country, this is not a position that will be sustained without continued investment and policies focused on supporting and incentivizing the next generation of biomedical discoveries, treatments, and cures,

The U.S. biotechnology industry is poised to be a major driver in an innovation-driven economy and we offer real solutions to our most pressing health care needs: curing disease, reducing costs, increasing quality, and ensuring that people enjoy not only longer lives, but better and more productive lives. Our biotech companies provide high-wage jobs at both public research institutions and in the biotech companies that typically locate near centers of academic research. The indirect effects of increased research funding on the regional economy are significant. For example, sponsored biomedical research directly generates jobs in the host institutions, and indirect and induced job creation in the region amounts to additional job growth. In fact, the nation's 1.42 million bioscience jobs support an additional 6.6 million jobs in the United States. resulting in a total employment impact of over 8 million jobs. 14

It is also critical that in an environment of budgetary constraint we do not lose sight of the fact that innovative medicines can actually help reduce healthcare costs. For example, Medicare is expected to spend over \$100 billion in 2012 caring for individuals suffering from Alzheimer's

¹⁰ Daveeman, Richard, "China Launches 'Mega Program' to Fund Drug Development," ChinaBio Today, 9 November 2008, http://www.chinabounday.com/articles/20081100

Buckley, Chris, "China to invest USS1.7 trillion over 5 years in 'strategic sectors': US official." The China Post.

²³ November 2011, http://www.chinapost.com.tw/business/asia-china/2011/11/23/323724/China-to.htm ¹² Hodgson, John, "62 billion IM1 launched with Faropean pharma," Nature Biotechnology 26, 717-718 (2008).

¹⁶ Dandekar, Vikas, "India Draws Lessons From China To Help Fosier Biotech Industry," PharmAsia News, 7 February 2012.

¹³ Battelle/BHO State Bioscience Initiatives 2010. Battelle/Lechnology Partnership Practice, May 2010.

disease. ¹⁵ Delaying the onset of Alzheimer's by just five years would save \$50 billion per year. ¹⁶ A similar calculus applies to numerous chronic, debilitating diseases, including heart failure, kidney disease, diabetes, and arthritis. By 2030, almost one out of every five Americans – some 72 million people – will be 65 years or older. And as almost 75 cents of every health care dollar spent is for taking care of individuals suffering from a chronic disease, it could not be clearer that we have a national imperative to find new solutions in how we treat patients and diseases.

In order to fully realize these potential benefits we must have a policy environment that fosters innovation. There are five policy areas necessary to enable us to deliver the next frontier of medical breakthroughs: 1) protection of intellectual property – to protect the main driver in securing private sector investment; 2) funding for basic research and an effective technology transfer system – to ensure that the latest scientific discoveries are able to be developed by industry and made available to patients; 3) funding opportunities for early-stage clinical research and development – to ensure that early-stage discoveries are fostered in order to encourage private sector investment; 4) tax and financial services policies that encourage investment and support biotechnology companies; and 5) a well-funded FDA with transparent and consistent regulatory processes that enable the timely, efficient, and predictable review of innovative medicines and allow for the use of modern scientific tools and methodologies that make the drug development processes more efficient. My testimony today will focus mainly on economic and regulatory proposals that would serve to preserve our position as global leaders in biomedical innovation.

INTELLECTUAL PROPERTY, TECHNOLOGY TRANSFER, AND FUNDING FOR RESEARCH: ENSURING A ROBUST PIPELINE OF BREAKTHROUGH TREATMENTS AND THERAPIES

Before I discuss new capital formation and regulatory proposals being considered by Congress. I want to highlight four laws currently in place that foster biomedical innovation.

http://www.alz.org/documents_custom/2012_Facts_Figures_Fact_Sheet.pdf

Alzheimer's Association, March 2012 Fact Sheet.

⁷ Journal of the American Certatries Society, 2002, 50:1-7, via Research! America, "Facts about Alzheimer's Disease," http://www.researchamerica.org/uploads/factsheet4alzheimers.pdf

Intellectual Property/Bayh-Dole

First. Congress should be applauded for the 2011 passage and enactment of the Leahy-Smith America Invents Act, or the "patent reform bill." Small biotechnology companies rely heavily on their patents to attract investment to fund the lengthy and expensive research and development process necessary to bring breakthrough medical therapies and other products to patients and consumers. Strong intellectual property protection is critical for these companies, and they will benefit from the improvements to our nation's patent system made by this law. However, even as we speak there continue to be attacks on intellectual property in Congress and in the Courts that could be devastating to the biotechnology industry, where intellectual property is often the only asset a company has while they spend many years researching and developing breakthrough medicines.

In addition to protecting intellectual property, it is imperative that we protect Bayh-Dole, the law that has for past three decades enabled the effective transfer of technology from basic research institutions to industry so that scientific discoveries can be developed into products that will benefit the public. Prior to enactment, the vast majority of university early-stage research languished because there was no protection against competition and thus little incentive for the private sector to invest the substantial sums of money required to develop these findings into products. The 2010 Association of University Technology Managers survey clearly shows the positive impact of the Bayh-Dole Act with 4,284 licenses executed, 657 new commercial products introduced, and 651 start-up companies formed in 2010.¹⁷ Additionally, a 2009 economic impact study showed that from 1996 to 2007 university-licensed products contributed more than \$82 billion to the GDP.¹⁸ This law is working well.

Therapeutic Discovery Project (TDP)

In March of 2010, Congress enacted the Therapoutic Discovery Project (TDP), a critical tax credit program designed to stimulate investment in biotechnology research and development.

¹⁷ AUTM Licensing Activity Survey: FY2010, Association of University Technology Managers, http://doi.org/10.1016/j.com/pn/1018.htm

http://www.autin.net/FY_2010_Licensing_Survey/7008.htm

The Beonomic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007.
David Roessner, Jennifer Bond, Sumiye Okuho, & Mark Planting, 3 September 2009.
http://www.orcgoubio.org/Portals/Odocs/Education/BIO_EDU_partnership_final_report.pdf

Under this program, small biotech companies received a much-needed infusion of capital to advance their innovative therapeutic projects while creating and sustaining high-paying, high-quality American jobs.

In total, the Therapeutic Discovery Project awarded \$1 billion in grants and tax credits to nearly 3,000 companies with fewer than 250 employees each. These small companies were eligible to be reimbursed for up to 50% of their qualified investment in activities like hiring researchers and conducting clinical trials. The impact of this funding was felt across the American biotech industry, as companies in 47 states received awards. The average company received just over \$200,000, an important shot in the arm during economically constrained times.

The Therapeutic Discovery Project was a significant step in the right direction by Congress to invest in growing the U.S. biotech industry and keep pace with our global competitors. Given the imbalance between the extraordinarily high demand by small biotech companies and the limited pool of funds. Those that Congress will extend and expand this oversubscribed program and assist more American companies in pursuing life-saving scientific breakthroughs and supporting American jobs.

SBIR Reauthorization

Lastly, I would like to the thank this Committee for its commendable work over the years and applaud its success in helping reauthorize the Small Business Innovation Research (SBIR) program last year. This reauthorization reinstated eligibility for a vast majority of companies that had been shut out of the program for the past decade, due to a regulatory ruling that made small companies who have multiple venture capital investors ineligible. SBIR provides a critical source of funding for emerging biotechnology companies in the early development stages of medical research; the changes included in the reauthorization will enable a larger number of small companies to compete for funding, thus ensuring that the program will be able to fund small biotech companies' projects that have the greatest potential to bring innovative medical treatments to the patients who need them. BIO looks forward to working with Congress as these reforms are implemented by the Small Business Administration and in the participating agencies and institutes.

RE-Engineering the Economic Model to Incentivize Biomedical Innovation

As I previously noted, U.S. biotech companies are facing financial uncertainty in a climate where other countries are increasing their investments and enacting intellectual property protections to encourage domestic biotech growth. While we still hold our place as the global leader, the competitive gap is getting smaller. For example, the U.S. currently holds the largest number of biotechnology patents overall, but we are 20th out of 23 countries in new biotech patents, with China and India ranking first and second. ¹⁹ These emerging powers are heavily investing in science, and particularly in biotechnology. Additionally, many countries in Western Europe are implementing biotech-friendly tax incentives, including lower corporate tax rates for innovative industries, as a means to grow their 21st century economies. This lag has put us at risk of losing our place at the forefront of this critically important and innovative economic driver.

Below I will briefly highlight some tax and capital formation proposals currently being discussed that would incentivize investment in small, emerging biotechnology companies and inspire further development on groundbreaking cures and treatments.

R&D Partnership Structures

Congress has historically provided tax incentives to high-risk industries as a means for encouraging investment in new endeavors. Biotechnology companies have among the largest capital burdens and longest development pathways of any industry, to determine whether their technologies will succeed. These high costs and long timelines can scare off investors who may be looking for investment strategies with earlier prospects for success. In the past, Congress has provided tax incentives that mitigate risk and enhance the returns of innovative development projects like those found in biotechnology companies. In particular, the growth of the biotech industry in the early 1980s was due in part to the ability of growing companies to pass through various tax incentives, including credits and losses, to their investors. These passive activity provisions allowed investors to realize an earlier return on their investment, thus incentivizing them to invest at an early stage. Amending the Internal Revenue Code of 1986 to allow certain tax incentives stemming from R&D to flow through from life science projects to their investors

¹⁹ "Gone Tomerrow!" A Call To Promote Medical Innovation, Create Jobs and Find Cures in America," The Battelle Technology Partnership Practice, 2010. Prepared for Fhe Council for American Medical Innovation.

would result in immediate tax benefits to investors and thus attract more investment in small biotechnology companies.

Section 382 Net Operating Loss (NOL) Reform

The long, capital-intensive development period intrinsic to biotechnology means that companies often undergo a decade or more of research and development without any product revenue prior to commercialization. During this time period, companies generate significant losses, which can be used to offset future gains if the company becomes profitable. However, Section 382 of the Internal Revenue Code restricts the usage of net operating losses (NOLs) by companies that have undergone an "ownership change." This section was enacted to prevent NOL trafficking, but small biotech companies are caught in its scope, as their reliance on outside financing and deals frequently trigger the ownership change restrictions. There are two reforms to Section 382 that would be beneficial to small biotechnology companies. First, exempt NOLs generated by qualifying research and development by a small business from Section 382 and second, redefine "ownership change" to exclude certain qualified investments, like those in rounds of venture financing. These reforms would allow small biotech companies to retain their NOLs and allow them to include them as tax attributes on the balance sheet, thus increasing their value when preparing for additional rounds of financing like mergers or initial public offerings.

Section 1202 Capital Gains Reform

Section 1202 provides a small business investment tax incentive wherein taxpayers may exclude 50% of their gain from the sale of a qualified small business stock that has been held for more than five years. This tax exclusion could be useful to small biotech companies by incentivizing investors to invest early and hold their investments longer. However, due to the valuable intellectual property and successive rounds of financing inherent in capital-intensive, innovative industries, small biotech companies do not meet the definition of qualified small businesses. Thus, Section 1202 does not provide investors an incentive to invest in small biotech companies. Changing the definition of "qualified small business" to include companies with gross assets up to \$150 million, indexing the cap to inflation, and excluding intellectual property and follow-on rounds of financing from the gross assets test would more accurately represent the capital-

intensive nature of innovative industries like biotechnology. Additionally, a graduated increase in the exclusion for qualified small business stock, rewarding investors who hold stock for longer and incentivizing them to continue to do so, would be extremely beneficial.

Section 197 Amortization Reform

Early-stage biotech companies often receive investments from strategic acquirers that are interested in an ongoing commercial relationship with the company. In such an acquisition, business acquirers often prefer to purchase the assets of a company. During an asset purchase, the acquirer may amortize certain intangibles under Section 197 provided that it continues using the intangibles in connection with the conduct of a trade or business. For intangibles that are subject to Section 197, the amortization of the tax basis is taken over a 15-year period. Accelerating this amortization period to a five-year period could encourage large company investors contemplating acquisitions of specific intangible assets of small biotech companies to invest at an earlier stage in the companies' research.

ENABLING MODERN FDA REGULATORY PROCESSES

PDUFA V and Modernizing FDA Legislative Proposals

As CEO of a small biotechnology company, I would like to take a moment to discuss how important timely reauthorization of PDUFA V is to the United States' biotechnology industry. To truly succeed, we need to have a strong, successful FDA. In 1992, Congress, industry, and the FDA worked together to create the Prescription Drug User Fee Act (PDUFA). This program ensures that FDA has the ability to hire reviewers to expedite the drug approval process by having industry pay "user fees." PDUFA has been a tremendous success. This year, the program is set for its fifth reauthorization, "PDUFA V," which will work to get the FDA back to the basics of approving lifesaving therapies and cures. PDUFA V will enhance the drug development and review process by increasing transparency and scientific dialogue, advancing regulatory science, and strengthening post-market surveillance. Most importantly, from the standpoint of innovative companies, our hope is that PDUFA V will provide patients and doctors with earlier access to breakthrough therapies. The FDA's commitment in the PDUFA V technical agreement to the principle that timely, interactive communication with biotechnology

and life science companies during drug development is a core Agency activity will be of great value, especially to small biotechnology companies such as mine.

While my testimony today will focus on Congressmen Stearns' and Towns' Faster Access to Specialized Therapies (FAST) Act, there are several proposals being considered by Congress that I also believe would serve to improve our ability to develop and deliver innovative medicines.

First, we need to have a well-funded FDA. While industry user fees play an important role in supporting FDA's medical product review program, user fees should be complementary and additive to a sound base of appropriated resources for the Agency, and I encourage ongoing Congressional support for the Agency.

Second, FDA's mission statement should be updated to reflect the Agency's critical role in advancing innovation. This would encourage FDA to apply its rigorous standards in the most innovation-friendly manner, striving to reduce the time of drug development, so that innovative treatments are made available to the patients who need them as expeditiously as possible. Additionally, we need to provide FDA with the authorities and structure that will better enable them to keep pace with the latest scientific advances and ensure innovative tools and approaches are integrated in the FDA review processes to ensure the timely and efficient review of innovative products, and to incentivize the development and utilization of modern scientific approaches to research and development.

Third, we need to encourage FDA to be more clear and consistent in its application of standards and its communications with drug developers. Currently, standards often appear to be inconsistently applied across different divisions of the Agency. In addition, clear reasons are not given when drugs are not approved, and what should be simple, rapid communications between the FDA and developers often become bogged down in processes that take months. Finally, and not least, critical written guidances for industry often take years to be published, if at all.

When application of drug approval standards and Agency decision-making are hard to predict, the burden on innovation increases. This is particularly problematic for smaller companies that have very limited resources and are dependent on only one or two programs. All of these issues

serve to prolong the drug development process and/or to inject so much uncertainty that investors are discouraged from investing in medical innovation.

Fourth, Advisory Committee and external expert conflict of interest rules should be reformed to provide FDA with greater flexibility and discretion to select the most appropriate advisors, consistent with the rules that apply to other federal agencies. As it stands, the lack of access to the best available scientific experts often deprives the Agency of the first-rate information it needs to make the best decisions on behalf of patients.

Fifth, processes should be implemented to ensure that the views of patient groups are solicited and heard within the drug approval process. The FDA is routinely called upon to make fine judgments regarding the balance between risk and benefit. This cannot be fully accomplished without consideration of how the patients themselves view a given circumstance that affects their health and lives. While the Agency properly is concerned about the risks of introducing unsafe drugs to the marketplace, another key risk in the risk-benefit equation is rarely considered: that of not making an effective therapy available to patients in a timely manner. Currently, patients may speak at public Advisory Committee hearings, but there is no requirement that their input be obtained for all drug reviews.

Finally, and not least, formal processes should be implemented to encourage the FDA to apply the Accelerated Approval pathway more widely. The Accelerated Approval pathway was implemented by FDA in 1992 in response to patient groups who, after engaging the public in a dialogue about benefits of new HIV/AIDS treatments, were successful in advocating for earlier access to these life-saving medicines. Accelerated Approval allows for earlier approval of new drugs that provide a benefit for patients with serious and life-threatening diseases based on a new product's effect on surrogate or clinical endpoints that are deemed "reasonably likely to predict clinical benefit." Under Accelerated Approval, FDA can approve the marketing of a drug to seriously ill patients based on earlier evidence of effect with a commitment from the sponsor to conduct further post-market studies to confirm and define the degree of clinical benefits to patients.

^{20 21} C.F.R. § 314.500; 21 C.F.R. § 601.40

The Accelerated Approval pathway has been a great success story, in part. While its use has been largely limited to certain disease areas (mainly cancer and HIV/AIDS), the pathway has benefited patients in those disease areas tremendously because it stimulated an explosion of investment in innovation. For example, there are now over 20 medicines for HIV/AIDS on the market. In oncology, FDA has granted Accelerated Approval to 49 new indications for 37 novel oncology drug products since 1995.²¹

There are many other serious and/or rare conditions that have been effectively excluded from the Accelerated Approval pathway. Accelerated Approval pathway needs to be modernized to incorporate the remarkable advances in life sciences that have been and will continue to be made, in such areas as genomics, molecular biology, and bioinformatics. These and other advances can enable novel drug development strategies, employing tools such as biomarkers, pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs – for example, adaptive clinical trials. Clarification of when and how these tools can be utilized in an Accelerated Approval pathway will not only incentivize drug development for serious and life-threatening diseases, but will encourage the development and utilization of still more tools and methodologies.

Enactment of H.R. 4132, the Faster Access to Specialized Treatments (FAST) Act would achieve these objectives.

Conclusion

Today I have discussed laws and proposals that would go a long way in fostering biomedical innovation in the United States. The decisions that Congress makes now will play a key role in whether or not we hold on to our global leadership in this area and maximize the economic and public health solutions that the biopharmaceutical industry has to offer. Thank you for the opportunity to share my thoughts with you today.

 $^{^{21}}$ Dr. Paul Kluctz, ODAC, February 8, 2011, the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC)

Mrs. BIGGERT [presiding]. Thank you, Dr. Cohen. Mr. Truitt, you are recognized for five minutes.

STATEMENT OF MR. MICK TRUITT, VICE PRESIDENT, LUDLUM MEASUREMENTS, INC.

Mr. TRUITT. Chairman, Ranking Member Edwards and distinguished Members of the House Subcommittee on Technology, thank

you for the opportunity to testify today.

My name is Mick Truitt, and I'm the Vice President of Sales, Marketing, and Business Development for Ludlum Measurements, Inc., a mid-sized company located in Sweetwater, Texas, a town of 11,000 people. I am here today to testify on behalf of the U.S. Chamber of Commerce, where I serve on the Corporate Leadership Advisory Council.

For over 50 years now, Ludlum has manufactured radiation detection equipment. We are recognized internationally for our reliable equipment, excellent customer service, and fair pricing. When disaster struck last year in Japan, Ludlum was one of the first in line to work hand in hand with the companies and people to help meet their needs. We continue to support the efforts being taken

for cleanup and to ensure people's safety.

Mr. Don Ludlum, the Founder and the President, was 29 years old when he started the company and today is still a very active participant in the business as the Company President. But most days, you won't find him in his business office. You will find him in Engineering, working on the next new design that Ludlum will present to the world. He told me not long after I started there that a company is either growing or dying. You can never just be standing still. That is even truer today in this global economy than it was on Valentine's Day in 1962 when Ludlum first incorporated.

Why Sweetwater? Simple economics. The people were friendly, and the bank was willing to take a chance on this 29-year-old and his idea of building a company. Now Ludlum employs 450 people in Nolan County and is the area's largest employer. Mr. Ludlum always liked the idea of keeping work in house, so when he needed more capacity, he built it internally, from making our own printed circuit boards to a full machine shop and plastic injection molding facility to specialized divisions that develop and manufacture both photomultiplier tubes and organic scintillator material that collects the radiation energy and turns it into an electronic signal that can be measured.

Ludlum has a staff of over 30 highly qualified engineers to make sure we stay up to date with our products. It is never an easy task to convince a young engineer that they should move to a small town in West Texas, and sometimes the best-qualified engineers are from outside of the United States. This is where the complications really begin.

Yes, our Nation's immigration laws impact the business community everywhere in this country and not just the major household

name companies and the titans of American industry.

Four years ago, when we were interviewing for an engineering position, we had a very bright young electrical engineer who had graduated with honors and had then gone on to get his Masters of Business Administration from the University of Texas. At that time, there were only three manufacturers of photomultiplier tubes in the world. He had worked for four years with one of them. This was almost too good to be true, but there was a snag. He was a Mexican citizen. It seemed that since his professional skill set was a perfect match for our needs, that the immigration process would be straightforward. However, to date, it has cost our West Texas company over \$17,000 in government fees and legal services to obtain and maintain lawful status for him. We are sponsoring this key employee for permanent resident status, but the green card process will take many more years to complete.

Meanwhile, as a direct result of this hire, we have expanded our sales and distribution in Central and South America from a little

over \$200,000 to over \$1 million annually.

In 2007, Ludlum acquired a company in the United Kingdom just outside of London. As this group grew, it became apparent we would need to expand our operation, but we wanted to expand here in the United States and not in the U.K. To do this, specialized equipment had to be purchased or manufactured. Once this manufacturing equipment was in place, Ludlum would need a highly skilled, qualified production engineer familiar with photomultiplier tube production to get the equipment up and operating and to train people to operate the equipment and test the end product. As this is a highly specialized market, there are few people in the world that could do this. Unable to find anyone locally, we depended upon our past experience of the people in the U.K. Instead of focusing on the fact that we had just completed a corporate acquisition, where it should be expected or at least acceptable for us to access our newly acquired staff and technology, we were faced with immigration delays. Three months and \$7,000 later, we finally were able to bring an appropriate engineer over on a regular basis to manage all the production line at our Sweetwater facility. This operation now employs another 20 Americans.

Ludlum Measurements now has only one competitor in the photomultiplier tube business, and you may have heard of this company. It is Hamamatsu. It would be impossible to compete in these global markets without engineers like these two, no matter

where they come from.

I am running behind. Another barrier to innovation and investment for our company is the uncertainty and potential increases of the individual marginal income tax rates. Ludlum is structured as a subchapter S corporation, which means that profits are passed through to the shareholders in the form of distributions and taxed at the individual's rate of income. It also means the rate of return on any reinvestment on those profits retained by the company will be impacted by the individual rate. As we attempt to plan for future long-term growth and expansion or paying off the principal on existing debt, individual marginal income tax rates do matter. Moreover, the uncertainty of whether those rates are dramatically increased at the end of this year or will be extended instills yet another layer of risk in the growth and investment decision-making process.

In conclusion, the decisions you make can help or hinder us. By that, I mean the laws you create will either cultivate a climate that

provides small- and mid-sized business owners greater confidence and certainty to invest, innovate, grow, and generate new jobs or one that does just the opposite. We desperately need elected office-holders who are on the right side of the debate and are willing to lead. I served in the United States Navy for 20 years and traveled the world aboard nuclear submarines. Between my military and business experience, I have been exposed to numerous countries and cultures around the globe. I am incredibly proud to be an American and strongly believe this Nation is still the greatest place to live and do business.

Thank you for the opportunity to testify, and I look forward to

your questions.

[The prepared statement of Mr. Truitt follows:]



100 Years Standing Up for American Enterprise U.S. CHAMBER OF COMMERCE

Statement of the U.S. Chamber of Commerce

ON: "Fostering the U.S. Competitive Edge: Examining the

Effect of Federal Policies on Competition, Innovation,

and Job Growth"

TO: The House Committee on Science, Space and

Technology's Subcommittee on Technology and

Innovation

BY: Mick Truitt, Vice President

Ludlum Measurements, Inc.

Sweetwater, Texas

DATE: March 27, 2012

The Chamber's mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity and responsibility.

The U.S. Chamber of Commerce is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector, and region.

More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. As a result, we are particularly cognizant of both the problems with which smaller businesses grapple, as well as those issues facing the business community at large.

Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum across many varied types of business and location. Each major classification of American business—manufacturing, retailing, services, construction, wholesaling, and finance—is represented. Also, the Chamber has substantial membership in all 50 states.

The Chamber's international reach is substantial as well. In addition to the U.S. Chamber of Commerce's 115 American Chambers of Commerce abroad, an increasing number of our member companies engage in the export and import of both goods and services and have ongoing investment activities. The Chamber favors greater international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on national issues are developed by a cross-section of Chamber members serving on committees, subcommittees, and task forces. More than 1,000 business people participate in this process.

Statement on

"Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth"

Submitted to

THE HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY SUBCOMMITTEE ON TECHNOLOGY AND INNOVATION

on behalf of the U.S. CHAMBER OF COMMERCE

By
Mick Truitt
Vice President
Ludlum Measurements, Inc.
Sweetwater, Texas
March 27, 2012

Chairman Quayle, Ranking Member Edwards and distinguished members of the Subcommittee, thank you for inviting me to testify before you today on the impact Federal policies have on the ability of U.S. businesses and entrepreneurs to compete, innovate and create jobs. I commend your efforts in holding this important hearing to better understand the effects this critical relationship between the decisions made, or not made, in Washington, DC and decisions made, or not made, in America's private sector.

I am Mick Truitt, Vice President of Ludlum Measurements, Inc. (LMI or Ludlum), a family-owned business headquartered in the West Texas town of Sweetwater which has a population of roughly 11,000. At LMI, I am responsible for global sales, marketing and business development. I am here to speak with you today on behalf of the U.S. Chamber of Commerce. I have the honor of serving on the U.S. Chamber of Commerce's Corporate Leadership Advisory Council. I am also active in the Sweetwater Chamber of Commerce where I just rolled off of their Board of Directors.

The U.S. Chamber of Commerce is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector, and region. More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. Therefore, the Chamber is particularly cognizant of the problems of smaller businesses, as well as the issues facing the business community at large.

Company Background

Ludlum Measurements, Inc. has been designing, manufacturing and supplying radiation detection and measurement equipment in response to the world's need for greater safety since 1962. In fact, we celebrated 50 years in business earlier this year on February 14. LMI is a family business. Don Ludlum, the company's founder, remains at the helm as President and all of his children are now part owners. I joined the LMI family in 2007. Throughout its five decade history,

LMI has developed radiation detection technologies and instruments to enhance the safety of personnel, secure borders, and protect the environment.

LMI services the nuclear power, energy research, medical, metals, emergency response and homeland security/defense markets. We are proud to offer one of the largest lines of radiation detection instrumentation available from any one company. After September 11, LMI was selected to provide approximately 300 vehicle radiation monitoring systems that are deployed along the entire northern U.S. border with Canada. LMI also supplies component parts for use in some of the current equipment utilized as part of the security systems in airports and borders around the world. In response to the crisis at the Fukushima Daiichi nuclear plant in Japan, our team at LMI was working seven days a week to prepare and ship thousands of our instruments to Japan to ensure the safety of the people and provide them with a sense of security. We did all we could to support the initial containment and will continue to support the Japanese people throughout the eventual cleanup efforts, and remain committed to helping make the world safer.

Ludlum has invested heavily into becoming a vertically integrated radiation detection company in order to better control costs, quality, and delivery times. Recent additions of in-house automated PC board assembly and plastic injection molding capability, plus photomultipier tube and plastic scintillation detector design and manufacturing, all contribute to this succeeding philosophy. Ludlum is the parent company and its divisions include: Eljen Technology, which manufactures a wide range of scintillator products such as plastic and liquid scintillators, wave length shifting plastics and acrylic light guides; ADIT, which designs and manufactures photomultiplier tubes for industry and the scientific community; ET Enterprises, which offers a wide range of photomultiplier housings, modular signal processing electronics and complete photon counting systems; Ludlum Medical Physics, which offers a unique product line created to more fully serve the medical physics community; Protean Instrument Corporation, which is a leading manufacturer of ultra-high performance sample counting systems for measuring alpha and beta activity at very low environmental levels; and West Texas Molding, which offers plastic injection molding services with an emphasis on short runs, quick turn-around deliveries and affordable pricing.

At our corporate headquarters in Sweetwater, Texas, Ludlum employs 450 people, making us the community's largest employer. We also have 100 employees at a facility in the United Kingdom and 10 in Knoxville, Tennessee. Typically, our annual revenues are \$65 million. Approximately 20% of our sales are international. We use distributor organizations located in country and currently are in over 80 countries worldwide. These numbers squarely put Ludlum in the range of companies known as mid-sized or middle market businesses. We are not a small business; nor are we a big business.

This is important to note because I believe many in Washington, DC do not understand the complex nature of the U.S. economy and business community. More often than not, those who pass the laws and write the regulations hold a simple, binary view of the U.S. business community: you are either small or other than small. Such a perspective fails to take into account the dynamic midtier section of American businesses. This is a critical shortfall in understanding when you recognize how important mid-tier companies are to the U.S. economy. Consider the following findings of a research initiative on the U.S. middle market (defined as companies with annual revenues ranging

between \$10 million and \$1 billion) completed by The Fisher College of Business at The Ohio State University and GE Capital:

- Middle market businesses contribute \$3.84 trillion annually to the U.S. private sector GDP—the equivalent of the world's fourth largest economy, just behind Japan but ahead of Germany.
- 80% of middle market businesses expect to grow over the next 12 months.
- More than one-third of U.S. workers are employed by middle market businesses.
- 82% of middle market businesses survived the recession.
- One in four big businesses were middle market companies just five years ago.

With such a sizeable contribution to U.S. employment and GDP, this dynamic middle market is clearly a vital segment of our private sector. Yet this is seemingly underappreciated and/or not understood by the decision-makers in Washington, DC. As I turn to focus on actual policy matters, I would ask that today and going forward you would be mindful of the impacts your decisions have, not only on small and big businesses, but on those in the middle as well. It is here that a great deal of innovation, sustained growth, and job creation is occurring.

There are numerous Federal issues that impact LMI's competitiveness both domestically and internationally. Today, I would like to focus on three of the most important: high-skilled immigration, taxes and trade. It is important to be mindful of the fact that my story, if you will, is similar to the stories of millions of small and mid-sized businesses across our nation.

High-Skilled Immigration

It may seem surprising, but, yes, a company with 450 employees in Sweetwater, Texas is directly impacted by the dysfunction of our nation's high-skilled immigration system.

Access to Human Capital, Regardless of Nationality

Perhaps most fundamentally, our high-skilled immigration system doesn't take into account the extent to which global collaboration is a premise in the 21st century for businesses of all sizes and stripes. In today's world, it doesn't take much to become a multinational company and develop a need for global collaboration among our own staff and between our staff and our customers. Not only do we sell our products in 80 countries, we have staff in two countries and, on occasion, we find the best qualified candidate for a job here in the U.S. doesn't happen to be an American citizen. At LMI, we have accepted the reality that the intellectual capital we need to do business does not reside solely in the United States with U.S.-born staff. A federal immigration policy which fails to recognize this simple fact does a disservice to America's business community.

The Chamber recommends an increased recognition of the importance of "human capital" in our high-skilled immigration policies. We see that human capital, which any business owner can tell you is vital to economic success, is not evenly distributed around the world. While there is ample human capital already in the United States, there are also enormous stocks of human capital—

and potential capital – found overseas in a variety of specialized fields that will greatly contribute to productivity growth in America. ¹

At LMI, if it relates to radiation detection instrumentation, we do it and we do it in-house, in Sweetwater. When we determined that we needed to have plastic injection molding capability we purchased a company that did that and brought the capability in-house. When we established that new types of plastic and liquid scintillators needed to be added to our production process, we established a new division that did that and brought the capability in-house. Sometimes, when we expand our Sweetwater operations and hire more Americans we also need a special, sophisticated skill set that we aren't able to find in the U.S. labor market. Hiring a foreign national to fill this need shouldn't be the confusing, difficult and sometimes impossible hurdle it is under current law. Instead, there should be a means to facilitate our ability to hire the best qualified high skilled professional we can get to come to Sweetwater, regardless of nationality.

In 2007, Ludlum was given an opportunity to purchase a UK competitor in the photomuliplier industry. Purchasing the competitor gave LMI an expanded product line while also limiting the number of photomulitiplier suppliers to 3 in the world. The purchase of the UK company also gave Ludlum a research and development group that is not available in the United States. As this was a growing market with fewer and fewer suppliers, down to 2 suppliers by 2008, we needed to expand the capacity of our UK product line because there was the opportunity for market share expansion for Ludlum.

While LMI could have expanded in the UK, instead we decided to bring that expansion to West Texas. To do this, specialized equipment had to be purchased or manufactured. Once this production equipment was in place Ludlum would need a highly skilled, qualified production engineer familiar with photomultiplier tube production to get the equipment up and operating and to train people to operate the equipment and test the end product. As this is a highly specialized market there are few people in the world that could do this. Unable to find anyone locally we sought out the past experience of our people at the UK facility. Initially, we thought it would be sufficient for one of our British engineers to simply attend a few meetings here as a B-1 business visitor, but it became evident that we required a production engineer to provide services on behalf of Ludlum in Sweetwater in order to establish the new production division. In fall 2009, we started the process to secure an L-1A intracompany transfer visa, so that one of our British engineers could come to West Texas to manage the new photomultiplier production function here. Three months and \$7,000 later we were finally able to have the engineering expertise onsite that was needed. Until our British colleague was able to travel back and forth to oversee our expansion and direct and advise our new technician staff, we were not able to fully take advantage of our acquisition, take our new production equipment out of storage, and make new U.S. hires for the new manufacturing operation. Today our photomultiplier tube expansion employs an additional 20 Americans.

In 2008, we were looking for an electronics engineer with experience in the radiation detection industry to come to Sweetwater and work in technical sales. It is exceedingly hard to find qualified, highly educated professionals who want to live in a small West Texas community. We were thrilled when a Mexican engineer who had an undergraduate engineering degree and a

¹ The Human Capital Imperative: Bringing More Minds to America, by Nick Schulz, U.S. Chamber of Commerce and National Chamber Foundation, January 2012.

graduate business degree from the University of Texas accepted our offer of employment. We had never had an engineer with an MBA even apply to join our company, so having this skill set in our engineering corps was a great asset. Our Mexican engineer graduated with honors in Electronic Engineering with the highest grade point average in the electronic engineering program (degree from the Instituto Tecnológico de Ciudad Victoria), worked for several years in Mexico in the radiation detection manufacturing industry, and completed a Masters of Business Administration from the University of Texas (at Brownsville). It seemed that because his professional skill set was a perfect match for our needs that the immigration process would be straightforward. However, to date, it has cost our West Texas company over \$17,500 in legal services to obtain and maintain lawful status for our Mexican engineer. We are sponsoring this key employee for permanent resident status, but the green card process will take many more years to complete. Meanwhile, as a direct result of this hire, we have expanded our sales and distribution in Central America from a little under \$200,000 to over \$1 million annually.

Ludlum's experience in having so much difficulty with the high-skilled immigration system is not unusual. Despite the fact that our hires of high-skilled immigrants directly contribute to job creation here in the U.S., the business community is faced with hurdles. For example, other Chamber member companies have experienced the following:

- A company manufacturing equipment conducts product testing in the United States after global teams develop new equipment specifications. A team of American engineers collaborating with company staff at design centers in North America, Asia and elsewhere comes together to complete product testing in the U.S. before manufacturing commences. Products are manufactured principally in the U.S. although some manufacturing is also conducted abroad. Products are principally sold outside the U.S. and most competing manufacturers in the particular industry are foreign corporations manufacturing solely outside the U.S. Visa petitions are denied for the foreign engineers working on the design team to come to the U.S. for product testing. Product testing is delayed, new product specifications can't be finalized, manufacturing engineering processes are delayed, and U.S.-based manufacturing jobs are reduced or new hiring delayed, while foreign competition is helped.
- A company has proprietary game software and a team of engineers working globally on updates and expansions to the product, with the product team based in the U.S. A foreign engineer already in the U.S. needs an extension of stay to continue his work on a key aspect of the game. A lengthy request for evidence is issued in the visa petition extension proceedings, questioning whether the worker qualifies to retain the same job for the same employer that he is already fulfilling, and in this case happens to hold several patents related to the game.
- A company designs and manufactures precision controls. It has three design facilities in the United States, two in Europe, and one in Asia. Individuals working on product design are typically in three or more locations, working jointly on different aspects of the project. The expertise of the engineers is not narrowly held within the company; instead a large number and percentage of the engineers are experts on precision controls and the company's proprietary systems. However, the expertise is narrowly held within the

industry and work on the design projects cannot be done without the engineers internal to the company. The company has regularly received denials over the last few years when it petitions for a visa to have an intra-company transfer come to the U.S. to continue working on new product designs with American staff.

- A company has a leadership program where key up-and-coming staff come to the U.S. to
 both facilitate U.S.-centric experience for the future management of the company and
 promote the cross-fertilization of ideas that are needed in a multinational company. Visa
 petitions are regularly denied, despite the interest of the American company to ensure its
 professional, degreed staff is exposed to American business methods.
- A company wants to open a fulfillment center in the U.S. where online orders can be
 processed and sent to North American customers. Visa petitions to bring in a handful of
 foreign staff well-versed in the company's internal processes are denied. While the
 foreign staff would have trained new American staff to be hired, the center cannot be
 opened without some experienced internal staff. Instead, the company considers
 opening a fulfillment center in Canada.

A Modest Proposal: More Green Cards for Scientists and Engineers

These types of examples show that current high-skilled immigration policies do not help foster America's competitiveness. In order to put a spotlight on this, the U.S. Chamber held an event in September 2011 to discuss Immigration and American Competitiveness, with a focus on high-skilled immigration issues. Mayor Bloomberg was the keynote speaker, and there was a panel of Chamber member companies discussing high-skilled immigration with Pia Orrenius, an economist with the Federal Reserve Bank at Dallas. When speaking at the Chamber event, Ms. Orrenius opined that "economists typically don't think that free lunches exist; but permitting more skilled immigrants to enter and stay is about as close as you can get to a free lunch."

From LMI's experiences, it does not seem our current federal immigration policies are aligned to get our nation's businesses at "the lunch table" to benefit from the economic benefit of skilled immigration. While broad-based immigration reform addressing and correcting the panoply of high-skilled immigration issues is not doable before the end of this election year, perhaps Congress can bite off one area where it is most obvious that our immigration policies need fixing regarding skilled immigrants. There appears to be an emerging consensus that action should be taken regarding foreign graduate students in the U.S. receiving Masters or Doctorates in the natural sciences and engineering from our fabulous U.S. universities.

Allocating more green cards for permanent resident status of these scientists and engineers who have job offers would be very sensible. Such a change would be responsive to one of the key

² Ms. Orrenius has written widely on immigration-related economic analysis. She often co-authors reports with Madeline Zavodny, a labor economist on the faculty of Agnes Scott College in Atlanta. Among other books and reports, Ms. Orrenius and Ms. Zavodny have co-authored *Beside the Golden Door*, 2010.

conclusions of the National Bureau of Economic Research, that "the U.S. economy will generate rising demand for highly-educated workers" through 2018.

The 2000 census indicated that immigrants constitute approximately half of the scientists and engineers in the U.S. with Doctorates, "a remarkable statistic given that they otherwise represent only 12% of the U.S. population." A focus solely on workers who possess a Doctorate is misplaced, though, since only about 2% of computer, mathematical, and engineering employment in the private sector is geared to individuals who have earned a Ph.D.5 Critically, more than 15% of workers in computer, mathematical, and engineering occupations in private industry are required to possess a Master's degree. 6 More specifically, by way of example, in computer science and mathematical science occupations, the job distribution is 6.9% of jobs require skills of high school diploma or less, 18.7% require skills based on some college, 10.5% require Associates level skills, 43.8% Bachelor's skills, 17.7% Masters skills, .8% Professional Degree skills, 1.7% Doctorate skills.

International students presently earn about one-half of all Master's level degrees from U.S. universities in fields corresponding to natural sciences and engineering occupations. 8 To the extent we want to ensure that American businesses have full access to the skill sets needed to create and retain jobs here at home, a streamlined process to have access to professionals who have been trained here, speak English, are acclimated to our culture and our business and research practices, want to stay here, and have a job offer from a U.S. employer would be a good start.

Coupling Education Reforms with Immigration Reform

High-skilled immigrants play a positive role in creating and retaining jobs in America. Critically, though, the U.S. Chamber believes that high-skilled immigration reform needs to be coupled with education reforms. As the U.S. Chamber pointed out in an Immigration Myths and Facts report last May, current immigrants make up a disproportionately large segment of both the population holding graduate degrees as well as those without a high school diploma. 10 To the extent that graduate education or university studies in certain fields is a prerequisite to the specialized skills and expertise needed in today's knowledge economy, pushing the interest and development

³ Future Skill Shortages in the U.S. Economy? National Bureau of Economic Research, July 2011. http://www.nber.org/papers/w17213

Immigrants' Success in Science Education and Careers, University of California at Berkeley's Center for Research on Teaching Excellence, http://escholarship.org/uc/item/2m14z6np#page-7 http://www.uschamber.com/sites/default/files/reports/16628_ImmigrationMythFacts_OPT.pdf

⁵ 2008 American Community Survey.

⁶ Distribution of workers possessing a Master's degree: 17.7% computer and mathematical science occupations, 16.9% architecture and engineering occupations. 2008 American Community Survey.

Future Skill Shortages in the U.S. Economy? National Bureau of Economic Research, July 2011, at Table 5.

http://www.nber.org/papers/w17213

⁸ See, Stuart Anderson, Keeping Talent in America, National Foundation for American Policy, October 2011, at Page 6, and Science and Engineering Indicators 2010, Chapter 2, Higher Education in Science and Engineering (Graduate Education, Enrollment, and Degrees).

Immigration Myths and Facts, U.S. Chamber of Commerce May 2011. http://www.uschamber.com/sites/default/files/reports/16628_ImmigrationMythFacts_OPT.pdf

Id. Page 1, citing Pia Orrenius and Madeline Zavodny, From Brawn to Brains: How Immigration Works for America, 2010 Annual Report (Dallas, TX: Federal Reserve Bank of Dallas, 2010), p. 6-7, http://www.dallasfed.org/fed/annual/2010/ar10b.pdf#page=3_

by U.S. students in these fields is also an economic imperative, starting at the K-12 level and continuing into higher education.

It is not just the "titans of American industry" which are looking for high-skilled workers and finding skill gaps in the domestic workforce. Middle market businesses have the same issues. For example, as described above, when LMI was looking for a technical sales engineer, the ideal skill set was an individual with an electrical engineering degree as well as business school training. To find someone with this skill set willing to be based in a small West Texas community is a challenge, and we jumped at the opportunity to hire a Mexican citizen with a top notch engineering degree from Mexico and a University of Texas MBA. Moreover, LMI needs highly skilled technicians, which we also frequently have had difficulty in locating in sufficient numbers.

Many Chamber companies in various sectors are aware of the education reform necessity and have their own education support programs. ¹¹ For example, one large diversified manufacturing company has taken the following steps: While the company typically recruits only graduate students for its professional jobs, it also has created a program where it seeks out highly qualified candidates with undergraduate degrees who the company puts through a two-year corporate professional management program for recruited university graduates in the fields of engineering, manufacturing, finance, and other business specializations to expose the participants to rotational assignments throughout the organization in order to develop both technical and management skills and create a diverse, knowledgeable global talent pool. Additionally, the company is a major contributor to U.S. colleges and universities and academic research projects.

The U.S. Chamber of Commerce has its own educational arm, the Institute for a Competitive Work Force (ICW), which promotes the rigorous educational standards and effective job training systems needed to preserve the strength of America's greatest economic resource, our workforce.

Last summer, ICW released a report addressing what kind of business involvement it would take to truly make a difference in K-12 schooling. Partnership is a Two-Way Street: What it Takes for Business to Help Drive School Reform 2 explains and analyzes how the business community can function as a critical customer, partner, or policy advocate in primary and secondary education. As discussed in the report, leaders in Texas, Tennessee, and Massachusetts adopted each of these roles, thus stepping up to make a big difference in K-12 schooling. In each case, business leaders talked seriously and bluntly with educators. They recruited well-respected experts to lead the reform efforts. They built sustainable structures, brought top-level executives to the table, and stayed engaged. They tackled tough questions, understood that some steps would be political and unpopular, and took the heat when there was pushback. Among its other ongoing activities, ICW conducts regional training for local and state chamber and business leaders, to create a leadership network in as many states as possible that is focused on the role business can play in improving

¹¹ See the Compete America coalition website for a summary of what some of the nation's largest high tech companies are doing to support education and workforce development. http://www.competeamerica.org/workforce/american-world-force

workforce.

12 Partnership is a Two-Way Street: What it Takes for Business to Help Drive School Reform, U.S. Chamber of Commerce, Institute for a Competitive Workforce June 2011
http://icw.uschamber.com/sites/default/files/Partnership%20is%20a%20Two%20Way%20Street_2011.pdf

education and workforce training. Also, ICW conducts an ongoing assessment of K-12 education in all 50 states and the District of Columbia through its *Leaders and Laggards*¹³ report.

Another recent report from ICW focuses on higher education. *Transforming Higher Education through Greater Innovation and Smarter Regulation*¹⁴ focuses on how academic programs and institutions must be transformed to serve the changing educational needs of a knowledge economy. The U.S. higher education system has long been one of the country's crown jewels. With the right leadership and policy choices, it will remain so. Higher education has not changed its basic structure and delivery model because it hasn't been forced to do so. However, an array of forces are now working to disrupt the traditional business model of higher education. Increasing international competition, a decline in government funding, changing demographics, and an increasingly mobile population are just some of the factors threatening the status quo. If innovation in higher education is discouraged through funding that fails to reward quality and outcomes, or simply thwarted by complacency within traditional intuitions, then the U.S. is likely to lose its edge to faster moving international competitors. In encouraging students to be ready for post-secondary education, ICW maintains active participation in coalitions focusing on both science and engineering as well as K-12 education, including Change The Equation, the Coalition for a College and Career Ready America, and the Business Coalition for Student Achievement.

Taxes

Another critical issue area for Ludlum is federal tax policy. There is absolutely no doubt that tax policy—both the burden and the uncertainty—impacts our competitiveness in what is a very competitive global marketplace. I want to focus on aspects of the federal tax code most pertinent to our business.

R&D Tax Credit

An essential factor in LMI's ability to stay competitive is a steadfast dedication to research and cutting-edge product development that has positioned us as a global leader in radiation detection devices. As a result of our commitment to innovation, many new, well-paying jobs have been created from investments we have made from advances in technology. The research and development (R&D) tax credit is one federal government policy that has further incentivized and assisted us in devoting additional resources toward research.

Regrettably, the recent anticipated yearly retroactive reinstatement of the R&D tax credit has served to undermine its salutary effects since it does not provide us certainty prior to our projected use. Even though the R&D tax credit has been in the Internal Revenue Code (Code) for many years and has been extended multiple times, the uncertainty of expired deductions and credits has had a material impact on our commitment to take full use of the benefit.

¹³ http://www.uschamber.com/reportcard.

¹⁴ Transforming Higher Education through Greater Innovation and Smarter Regulation, U.S. Chamber of Commerce, Institute for a Competitive Workforce May 2011 http://icw.uschamber.com/sites/default/files/HigherEducationReport_final_high%20res.pdf

Moreover, many research projects are budgeted and planned for on a three- to five-year basis. In order for us to map out a long-range business plan for future innovation and investment, we need reasonable assurances of the federal government's commitment in reinstating the tax credit beyond one-year increments. Not having a permanent R&D tax credit erodes the confidence and certainty needed to dedicate the maximum amount of resources possible for riskier, yet potentially more rewarding, long-term scientific endeavors.

Additionally, we find the complex accounting requirements required to take full advantage of the credit creates unproductive and time-consuming paperwork demands that reduce the ability for us to use the maximize amount of the credit that we would otherwise be allowed. Simplifying the bookwork needed to take advantage of the credit would provide our scientists and engineers more time to do what they do best, innovating and creating jobs rather than subjecting them to overwhelming paperwork requirements.

Nevertheless, the R&D tax credit has been in the Code for almost 30 years and is a proven incentive for driving investment in R&D, encouraging long term capital investment, creating jobs, strengthening the economy, and spurring innovation in the United States. 15 In 1981, the United States was one of the first countries to add an incentive for research and development to the Code. For a period in the 1980's, the United States was at the forefront of R&D incentives. However, other countries soon followed, introducing their own R&D incentives. By 2008, the United States' R&D tax incentive ranked 17th overall amongst OECD nations. 16

Other countries have moved to incentivize R&D, through adoption of super deductions, credits, and patent and innovation boxes. These countries use these incentives to promote the relocation of R&D operations to their countries as part of "innovation-led economic development strategies."17 Thus, the United States' R&D credit must compete with the aggressive incentives marketed by other countries. The failure to, at the very least, simply maintain our current credit increases the risk that the jobs, capital investment, and intangible property developed in the R&D process will move outside our borders.

Further, as Congress considers changes to the tax code in the context of fundamental comprehensive tax reform they should strive for a more permanent provision to incentivize R&D. Taxpavers need stable and predictable rules they can rely upon until fundamental permanent reforms can be made. We strongly urge Congress to act quickly to extend this longstanding policy and prevent unnecessary damage to the economy and job creators.

¹⁵ See, e.g., U.S. Department of the Treasury, "Investing in U.S. Competitiveness: The Benefits of Enhancing the Research and Experimentation (R&E) Tax Credit" (March 25, 2011) (noting that the R&D credit in its current form offers a cost-effective way to encourage research spending and supports high-wage jobs). See also Carroll, Prante, and Quek, "The R&D Credit: An effective policy for promoting research" (September 2011) (estimating the higher wage and employment impacts of the R&D credit).

¹⁶ See Information Technology and Innovation Foundation, "Create Jobs by Expanding the R&D Tax Credit," (January 26, 2010).

The Tax Code and Marginal Rates

Another barrier to innovation and investment for our company is the uncertainty and potential increase of the individual marginal income tax rates. LMI is structured for tax purposes as a Subchapter S corporation which means that profits are passed through to the shareholders in the form of distributions and taxed at the individual's marginal income tax rate. It also means that the rate-of-return on any reinvestment on those profits retained by the company will be impacted by the individual rate.

As we attempt to plan for future long-term growth and expansion or paying off the principal on existing debt, individual marginal income tax rates do matter. Moreover, the uncertainty of whether those rates will dramatically increase at the end of the year, or will be extended, instills yet another layer of risk in the growth and investment decision making process. Any potential increase in the rates will increase the cost of capital obtained through the retention of earnings, which in turn, decreases the return on any capital investment. Since it is uncertain as to whether or not some or all rates will increase, we must also take this possibility into account in determining the feasibility of the project.

The bottom line—any increase in marginal income tax rates and the uncertainty of whether increases will take place has a chilling effect on our ability to grow, expand and create jobs.

Besides individual marginal rates, many other provisions of the Code are currently set to automatically increase at the end of the year which will complicate our business decisions. Increases in capital gains tax, tax on dividends, the estate tax, the Alternative Minimum Tax (AMT) patch, and the uncertainty of how these provisions will be treated going forward will complicate our ability to innovate, grow and create jobs.

Additionally, some lawmakers are discussing undertaking corporate only tax reform. Having a tax system where marginal corporate rates are not synchronized with the individual rates pass through entities are subject to, would cause S corporations, such as LMI, to be forced to dedicate significant time and resources to financial engineering to address the lack of rate parity. Further, if certain tax expenditures were eliminated to fund a corporate rate reduction, pass through entities would see a de facto tax increase from the loss of these credits and deductions with no corresponding marginal rate reduction. Accordingly, any tax reform proposals must be comprehensive and address both corporate and individual rates.

Trade

For LMI, doing business beyond the domestic U.S. market is a critical part of our existing business model as well as a key part of our growth strategy. As I mentioned earlier, through distributor organizations we sell our products in more than 80 countries with these international sales contributing approximately 20% of our annual revenues. Like thousands of other American businesses, we understand the opportunity the global marketplace offers: outside our borders are markets that represent 80% of the world's purchasing power, 92% of its economic growth, and 95% of its customers. And we know first-hand that trade is not just important to big companies. Often overlooked in the U.S. trade debate is the fact that more than 97% of the quarter million U.S.

companies that export are small and medium-sized enterprises, and they account for nearly a third of U.S. merchandise exports, according to the U.S. Department of Commerce.

Export-Import Bank

The Export-Import Bank of the United States (Ex-Im) has been of value to LMI in helping us complete international deals and generally enabling us to be more competitive globally. In FY 2011, Ex-Im authorized more than \$4.5 billion in export credit financing for Texas companies, supporting over 400 companies in the state, with over half of those being small business. In fact, Texas ranks number 1 in the country for small business financing. Here at LMI, Ex-Im has supported \$15 million of our export sales over the past five years.

I want to urge Congress to approve a four-year reauthorization of Ex-Im before its temporary reauthorization expires on May 31. Failure to do so would disadvantage Ludlum and U.S. companies—small, medium, and large—in foreign markets.

Ex-Im has a proven record of success. Far from being a burden on the taxpayer, Ex-Im turns a profit for the American taxpayer. Since 2005, Ex-Im has returned more than \$3.4 billion to the Treasury above all costs and loss reserves, including \$700 million in FY 2011 alone.

Nor does Ex-Im only help big business. In fact, small businesses account for 87% of Ex-Im's transactions; further, these small business transaction figures are in addition to the tens of thousands of small and medium-sized businesses that supply goods and services to large exporters. In FY 2011, Ex-Im provided more than \$6 billion in financing and insurance for U.S. small businesses —an increase of nearly 90% since FY 2008. Ex-Im has set the goal of adding 5,000 new small businesses to its portfolio by 2015.

Another myth holds that Ex-Im competes unfairly with private financial institutions. In fact, Ex-Im covers critical gaps in financing for U.S. exports to developing countries where commercial-bank financing is unavailable or insufficient. Ex-Im also acted to fill the void when the availability of private-sector trade finance fell by 40% during the 2008-2009 financial crisis. In the aircraft sector, a new multilateral agreement doubled the fees for export credit financing, thereby addressing the concern that some export credit financing was below market rates.

Ex-Im lending exposes the taxpayer to very little risk. Borrowers have defaulted on less than 2% of all loans backed by Ex-Im since its inception in 1934, a default rate lower than commercial banks. Ex-Im loans and guarantees present very low risks because they are backed by the collateral of real goods for which a buyer has already been found and a price has been agreed. As a result, Ex-Im poses none of the risks to taxpayers that, for instance, government-sponsored enterprises in the housing sector ultimately did.

Failure to reauthorize Ex-Im would amount to unilateral disarmament in the face of other nations' aggressive trade finance programs. For example, the export credit agency in Canada has extended three times as much export financing as Ex-Im; Japan more than five times; and China an estimated eleven times. Failure to reauthorize Ex-Im will put billions of dollars in U.S. exports and thousands of American jobs at risk.

Trade Promotion Authority

Looking beyond the immediate priority of reauthorizing Ex-Im, a pro-jobs trade agenda that includes more market-opening agreements, such as those recently approved with South Korea, Colombia, and Panama, should be a focal point for a Congress concerned about the competitiveness of U.S. businesses, economic growth and job creation. While I am not a trade specialist, I know enough to recognize that first the president needs the authority to negotiate such agreements—Trade Promotion Authority (TPA). Congress has granted every president since FDR the authority to negotiate market-opening trade agreements in consultation with Congress.

TPA lapsed in 2007. That's unacceptable; every American president needs TPA, and every president should have it. It sends a wrong signal to potential partners who won't negotiate seriously if they know agreements could be picked apart by Congress.

Without TPA, the United States is relegated to the sidelines as other nations negotiate trade agreements without us—putting American companies at a *competitive disadvantage*. Already, more than 300 free trade agreements are in force around the globe, but the United States is a party to just 14 such agreements covering 20 countries. And that includes the most recent three, which have yet to be implemented. To be competitive globally, grow our economy and create U.S. jobs, we must be in the game and getting back in it starts with TPA.

Other Opportunities

LMI does a considerable amount of business in Asia and Europe. I am pleased that the United States has a seat at the table for negotiations of the Trans-Pacific Partnership (TPP) which are underway. It's a great place to start. Asia accounts for half of the world's population and is projected to account for a large share of its economic growth for years to come. To boost U.S. exports and create jobs at home, the United States needs to improve its access to Asian markets.

Asian nations are designing a new architecture for trade in the global economy's most dynamic region — threatening to draw "a line down the middle of the Pacific." The TPP is our chance to ensure the United States is in the game in Asia. Embracing nine countries today, many hope additional countries will accede over time. The United States must be engaged, it is critical to our competitiveness and economic growth.

As we consider new trade accords, Europe calls out for attention. Indeed, the European Union is by far America's largest international economic partner and, in the size of its economy, our only true economic peer. It is also an important market for Ludlum.

Last year, the Chamber supported a study to gauge the potential benefits of eliminating tariffs between the United States and the European Union. The study found that eliminating transatlantic tariffs would boost U.S.-EU trade by more than \$120 billion within five years. It would also generate GDP gains of \$180 billion — a budget-neutral boost to the U.S. and EU economies. I support the proposal for a Transatlantic Economic and Trade Pact that eliminates tariffs, ensures compatible regulatory regimes, and addresses investment, services, and procurement.

Conclusion

I am told that given the existing political realities in Washington, DC, it is difficult to find common ground and get things done. I want to remind you that business owners across our nation and the men and women they employ face great challenges every day as well. Yet we find a way to overcome hurdles, make progress, and ultimately achieve solutions. I do not think it is too much to ask of our elected officeholders to do the same. Just as we have men and women and their families at LMI who directly depend on us for their jobs and livelihood, you have a nation of entrepreneurs and business owners who are impacted by your ability (or inability) to foster a policy and regulatory environment that encourages risk-taking, investment, innovation and job creation. The bottom line is that the decisions you make can help or hinder us. By that I mean the laws you create will either cultivate a climate that provides entrepreneurs and small and mid-sized business owners greater confidence and certainty to grow and generate new jobs, or one that does just the opposite.

We desperately need elected officeholders who are on the right side of that debate who are willing to lead. I served in the United States Navy for 20 years and travelled the world aboard nuclear submarines. Between my military service and business experience, I have been exposed to numerous countries and cultures around the globe. I am incredibly proud to be an American and strongly believe this nation is still the greatest place to live and do business.

I am hopeful that each member of this Subcommittee as well as all of your colleagues in the House and Senate will commit to advancing legislation in the areas of high-skilled immigration, tax, and trade policies to boost the competitiveness of U.S. businesses while also coming together to eliminate onerous mandates and regulatory burdens which saddle businesses with hurdles that actually hamper economic growth and job creation.

One of the most significant areas where Congress can legislate reforms with a direct impact on expanding job creation is high-skilled immigration reform. Thus, there is an economic imperative for employment-based immigration reform.

The Chamber applauds the Subcommittee for holding this hearing, and thanks you for this opportunity to testify. I look forward to your questions.

Mrs. BIGGERT. Thank you, Mr. Truitt. Mr. Brandt, you are recognized for five minutes.

STATEMENT OF MR. THOMAS M. BRANDT, JR., SENIOR VICE PRESIDENT AND CFO, TELECOMMUNICATIONS SYSTEMS, INC.

Mr. Brandt. Thank you. Mr. Chairman, Ranking Member Edwards, Members of the Subcommittee, I am Tom Brandt, Chief Financial Officer of TeleCommunications Systems, an entrepreneurled, Annapolis, Maryland-based wireless communication technology business, which now employs about 1,500 professionals and holds more than 200 patents. I am also here before you today representing TechAmerica, the Nation's leading technology advocacy organization representing over 1,000 U.S. companies committed to innovation. In my testimony today, I will share TechAmerica's insights on some policy areas where Congress can act to help advance America's innovation economy.

TechAmerica has been working to advance a competitiveness agenda for U.S. policy since collaborating with Leader Pelosi and others in 2005 when we published "Losing the Competitive Advantage: The Challenge for Science and Technology in the United States." My hope is that these latest recommendations will help to inform public discussion and facilitate meaningful debate toward a

national technology vision and strategy.

The best hope for the United States to maintain its edge in an increasingly competitive world is by fostering and expanding our most prized intellectual asset, innovation. Over the past 30 years, innovation has given the United States and the rest of the world wave after wave of technological advancement and generated millions of high-skilled jobs. On average, each technology job supports three jobs in other sectors of the economy. The multiplier effect for information technology jobs is even higher, nearly five to one.

Information technology has a proven track record of economic success having recently accounted for more than a third of U.S. gross domestic product growth and nearly two-thirds of corporate

capital investment.

Access to capital, strong basic research, the best and brightest minds, and an infrastructure that supports the entrepreneur are four key elements that have allowed the United States to thrive on the basis of innovation.

Foreign governments, however, are increasingly aggressive in promoting favorable tax policies, improving their legal accounting/intellectual property structures, and boosting their R&D spending to foster innovation in their countries. The United States needs to meet the challenge of foreign competitors or risk losing our edge. To maintain our Nation's competitive advantage, we must update public policy to support what has made us successful: improving access to capital with smart tax policies, increasing support for our basic R&D, improving math and science education, and supporting immigration and opening new markets.

One of the greatest challenges facing new start-up companies is gaining access to enough capital to get off the ground in the early years and then fueling growth without prematurely ceding control to a bigger, less entrepreneurial owner.

About 25 years ago, my employer started up our company with his wife and a childhood friend. Critical steps in growing our company were venture capital investment followed by our IPO 12 years ago. We now employ about five times the 295 employees in our 2000 prospectus, and we were very fortunate to raise our capital shortly before changes in the environment sharply raised the bar

on access to such capital for similar stage companies.

Reduced obstacles to investor capital for small growth companies can make a major difference. The United States also needs to reform the income tax code. Other nations have adjusted their codes to incentivize innovation, attract investment, and enhance the competitiveness of companies within their borders. In just days, the United States will lead the world with the highest corporate tax rate. We need to change that. The R&D tax credit is a modest but Byzantine provision that can help incentivize innovation, but it expired again in 2011. The United States needs to make it stronger and make it permanent. The last major corporate tax reform took place 25 years ago, long before many of today's U.S. technology-based companies were even in existence. TechAmerica looks forward to working with Congress and the Administration on ways to modernize the tax code.

The government has a critical role in the area of basic research. From this pipeline of advances in information technology, life sciences, and now clean energy, technology enterprises have historically drawn many innovations. Often, early-stage research into new discoveries is first funded with federal dollars in a university or government lab and then commercialized by angel or venture investors.

Prudent application of intellectual property laws can have an important impact on services to the public. For example, I am confident that all here recognize the importance of 911 technology, a vital national service that protects the lives and property of every American and of which my company is a provider. Today 911 is threatened by what the Federal Trade Commission has termed patent assertion entities. These companies have increasingly focused on government-mandated 911 services by wireless carriers as proof of infringement with significant financial consequences to both the carriers and their 911 vendors. I encourage you to investigate and resolve the 911 patent problem before it irreparably harms America's safety and security by disrupting the 911 system.

In addition to supporting basic research, government must also support the entrepreneurial and technical talent that brings this research to life. TechAmerica wholeheartedly supports investing to improve math and science education for U.S. students, particularly in grades K through 12. Other countries have been devoting more

resources to STEM education for some time.

It is also critical that we reduce obstacles to the best and brightest scientists and entrepreneurs from all over the world who want to come to the United States. The U.S. high-tech industry and the 5.9 million workers that it employs rely on international trade and investment for continued growth, innovation, and job creation. Encouraging international trade buoys our GDP, enhances produc-

tivity and boosts the ability of small businesses to innovate and create good U.S.-based jobs.

In conclusion, the technology industry remains committed to doing our part to ensure that the United States remains the leader in the innovation race, but we need the right policies in place. TechAmerica looks forward to working with Members of this Committee, Congress, and the Administration to support the best and brightest ideas that continue to fulfill a robust pipeline of innovation for our country. I thank the Committee for this opportunity to discuss these issues with you today, and I am happy to answer questions.

[The prepared statement of Mr. Brandt follows:]

PREPARED STATEMENT OF MR. THOMAS M. BRANDT, JR.



Prepared Testimony and Statement for the Record of

Thomas Brandt
Senior Vice President and Chief Financial Officer
TeleCommunication Systems, Inc.

On Behalf of TeleCommunication Systems, Inc. and TechAmerica

Before the

The Science, Space and Technology Committee Subcommittee on Technology and Innovation Committee on Science, Space and Technology U.S. House of Representatives

Hearing on

The Effect of Federal Policies on Competition and Innovation

March 27, 2012 2318 Rayburn Building

Mr. Chairman, Ranking Member Edwards, and Members of the Subcommittee, my name is Tom Brandt, and for the past 15 years I have been the Chief Financial Officer of TeleCommunication Systems Incorporated, based in Annapolis, Maryland. Our company is in the wireless communication technology business, selling highly reliable and secure solutions to wireless carriers and government agencies including military special operations and 9-1-1 services for public safety. I work for the founder and CEO, an African American 1978 alumnus of the naval academy, who started the company in 1987 and initially grew it with the help of some SBA programs. We raised venture money in part from a Small Business Investment Company ("SBIC") in the late 90s, went public in 2000, and now employ about 1,500 people and hold more than 200 patents.

In my testimony today, I am also representing TechAmerica, the leading advocacy organization for U.S. companies committed to enterprise based on technology and innovation. My company is one of about 1,000 member companies of all sizes comprising the technology industry's only grassroots-to global network, with presence in state capitals around the United States, Washington, D.C., Europe (Brussels) and Asia (Beijing). TechAmerica's roots go back to an initiative by David Packard in the late 1940s to link the emerging Silicon Valley to Washington.

Thank you for allowing me the privilege of sharing with you perspectives on the opportunities and challenges surrounding our nation's innovation policies. The U.S. technology industry is the driving force behind productivity growth and jobs creation in the United States and is the foundation of the global innovation economy. I appreciate this Committee's attention to this topic, and I commend you for advancing the dialogue on how our nation's innovation policies can drive growth in our economy, and enable American companies to successfully compete in the global market to meet demands for the future.

I would like to submit for the hearing record TechAmerica's "Technology Roadmap," which highlights policy areas where Congress can act to help advance America's innovation economy. Our hope is that the recommendations included here will help to inform public discussion and facilitate meaningful debate toward the development of a national technology vision and strategy.

The U.S. Innovation Economy

The importance of innovation—creating new ideas, products, and services—cannot be overstated. And in this global, highly competitive economy, it is increasingly the intangible inputs of research and development ("R&D"), education, and entrepreneurial risk-taking that drive that growth. Innovation is key to creating new industries, and therefore key to the creation of American jobs.

Our country is home to institutions that have nurtured many of the best and brightest minds on the planet. And that intellectual prowess has benefited our economy in countless ways. Yet we all know that the process of bringing innovation to life is not simple. There is a critical path along which many stakeholders – including entrepreneurs, technologists and policy makers – play important roles.

Historically, our government has helped pave that path with policies that encourage innovation on many levels. Yet the global environment has changed significantly in the last decade and the United States is no longer as dominant in entrepreneurship and innovation. The best hope for the U.S. to maintain its edge in rising global competition is by fostering and expanding our most prized intellectual asset: innovation.

Over the past 30 years, innovation has given the U.S. and the rest of the world wave after wave of technological advancement and generated millions of high-skilled jobs.

On average, each tech job supports three jobs in other sectors of the economy. The multiplier effect for information technology jobs is even higher — nearly 5 to 1. Information technology has a proven track record of economic success, having recently accounted for more than a third of U.S. gross domestic product growth and nearly two-thirds of corporate capital investment.

Information and communications technologies (ICT) generate some of the fastest-growing business sectors, based on continuous innovation. The United States is the leading innovator in this space, responsible for a third of all ICT-related patents filed and over 70 percent of global software research and development. To ensure that successive waves of innovation begin in the U.S., and that U.S. workers benefit from "the next big things," we must evolve the necessary infrastructure and environment.

The ICT sector represented by TechAmerica wants to help ensure that high quality new U.S. jobs emerge in a global, competitive and technology-based economy, through encouraging and rewarding high skill levels and entrepreneurship. Unfortunately, the U.S.'s ability to adapt, compete and innovate alongside emerging workforces in China, India and other countries is impeded by a systemically weak education system, a dearth of R&D funding, a visa policy that limits access to the brightest foreign-born minds, and a business climate heavy with regulatory and tax burdens. Our public policy should be crafted to enable the U.S. to remain the world's innovation leader.

Access to strong basic research, the best and brightest minds, access to capital, and an infrastructure that supports the entrepreneur are in fact the precise components that have historically allowed the U.S. to thrive on the innovation spectrum. And these same drivers will determine our fate going forward.

It is important to recognize that the global environment for innovation has changed dramatically in the last decade – creating both opportunities and threats to U.S. innovation. Technology has indeed made the world flat and our companies today all employ global strategies when it comes to markets, product development and operations. The global markets offer our companies tremendous growth opportunities – provided the U.S. maintains open trade provisions. Yet, at the same time, there has been a significant rise of venture capital and entrepreneurial activity in regions outside the United States such as Asia, Eastern Europe and South America. As entrepreneurialism grows on a global scale, we face a new competitive environment in which innovation can be developed anywhere.

Foreign governments are increasingly aggressive in promoting favorable tax policies, improving their legal, accounting and intellectual property structures, and boosting their R&D spending to foster innovation in their countries. The U.S. needs to meet the challenge of foreign competitors or risk losing our technological edge.

A Tax Code To Help Our Companies Be Globally Competitive

Many nations have adjusted their tax codes to incentivize innovation, attract investment, and enhance the competitiveness of companies within their borders. Yet, in just days, the United States will lead the world with the highest corporate tax rate. We need to change that. Lower corporate tax rates would help U.S. companies attract capital to compete, as well as encourage

foreign companies to invest in the United States, resulting in increased employment and higher wages for American workers.

Other countries are aggressively encouraging research and development activities, but the U.S. research and development credit expired – again – at the end of last year. This incentive influences the choice of location among companies looking to open or relocate research facilities. As foreign governments actively recruit American companies to move their research operations abroad, the credit helps to encourage companies to invest in R&D using employees in the United States. It is time for Congress to make this incentive clear, predictable and permanent.

In order to grow and compete, U.S. companies must take their ingenuity and investment well beyond our borders because 95 percent of the world's population lives outside the United States. Today, even small business is global business and our nation's technology companies must be able to thrive in the global market or we risk falling further behind other world-class competitors in the tax arena. The reality is expanding operations overseas enhances U.S. productivity and is essential for future growth, and this is why TechAmerica supports moving towards a competitive territorial system. Thankfully, Congress and the Administration have begun the process of considering comprehensive tax reform, recognizing the competitive disadvantage our current system inflicts on our global businesses.

A Permanent and Strengthened R&D Credit

We believe that investing in research, especially during these challenging times, is crucial to repowering the American economy. The R&D tax credit has a proven history of encouraging additional investments in research and promoting U.S.-based, high-wage job growth in companies of all sizes. It is disproportionately difficult, expensive and risky for smaller companies to engage in R&D activities, but permanent enactment of a strengthened credit would go a long way toward encouraging companies of all sizes to make R&D investments. Ultimately, it would stimulate U.S. innovation and lead to growth in jobs, wages, consumption and exports – all contributing to a stronger economy and a higher standard of living for American workers.

Strengthening and permanently extending the R&D tax credit, which expired at the end of 2011 and has yet to be renewed, would provide the certainty and resources business owners need in order to be able to plan and invest in U.S.-based research with certainty well into the future.

This will help stimulate short-term business investments with long-term benefits to the U.S. economy.

Since the R&D tax credit is only available for certain qualified research performed in the United States, it is really a U.S. jobs provision, since more than 70 percent of the benefits of the credit are attributable to the wages and salaries of workers performing research in the United States. The enactment of a strengthened and permanent credit will serve to both maintain and create new high-paying, high-skilled research jobs in the United States.

Federal Investment in Basic Research

The government also has a critical role to play in the area of basic research. It is from this pipeline of scientific advances in fields such as information technology, life sciences and now, clean technology, that the technology industry has historically drawn many innovations. Often, early stage research into new discoveries is first funded with federal dollars in a university or government lab and then commercialized by angel and venture investors.

For these reasons, TechAmerica has supported the America Competes Act and continues to support the spirit in which it was passed in 2007. In order for the U.S. to maintain its competitive advantage and economic leadership, we must continue to aggressively promote a public policy agenda that rewards risk takers and embraces innovation at a national level. The United States spends more than any other nation in the world on R&D, but its relative position (measured by the share of such investment in national income) has been falling even as other countries increase their investments in research.

Investment in R&D is a significant driver of technological progress and economic growth. U.S. industry and the Federal Government are the primary pillars of financial support for the U.S. R&D. Sources of these basic research funds have historically included the NIH, NIST, DOD, DARPA and, most recently ARPA-Energy. Continuing to support federally funded research through these agencies will nurture the symbiotic relationship between the government and private investment capital. Essentially, the private sector picks up where government funding leaves off. We hope to see a continued commitment at that level or above going forward, so that American companies can bring the exciting work taking place in those labs to the global market. We also ask that policy makers continue to exhibit the same patience they have shown in the past for the high-risk and long-term nature of the innovation process. This support is critical to our ability to see our projects through to success. TechAmerica is pleased to see that

federal R&D investment would rise to \$142.2 billion under the President's FY 2013 budget request, representing a 1.2 percent or \$1.7 billion increase above FY 2012 estimated funding levels.

TechAmerica urges the Committee to remain committed to doubling the budgets of the National Science Foundation, Department of Energy Office of Science, and the National Institute of Standards and Technology labs. The President's Plan for Science and Innovation (a key pillar of A Strategy for American Innovation announced in September 2009 and revised in February 2011), the America COMPETES Act of 2007 (P.L. 110-69), and the America COMPETES Reauthorization Act of 2010 (P.L. 111-358) have all identified NSF, DOE SC, and NIST as critical to preserving America's place as the world leader in innovation. Congress and the President have shown strong support for these agencies, but appropriations in recent years have not achieved the sustained increases authorized by the COMPETES legislation.

TechAmerica supports the President's FY2013 discretionary funding request for NIST of \$857 million (excluding transfers), an increase of \$106 million over FY 2012. More than half of the proposed increased funding would be focused on advanced manufacturing research both at NIST laboratories and through a new industry-led consortia program. We believe this budget request will address pressing needs for standards and measurement work in emerging technology areas and provide seed funding to encourage industry and academia to come together to address common technology problems too large for individual institutions to tackle. Moreover, this budget is consistent with the President's Plan for Science and Innovation and the goals of the America COMPETES Reauthorization Act of 2010, both of which call for significant increases in basic federal R&D funding to make America more competitive.

TechAmerica would like to also voice support for a \$10 million NIST initiative in the President's FY2013 Budget that will support the technological infrastructure, including standards, underpinning broadband communications networks, which have become as essential to today's economy as the electrical power grid was to the Industrial Revolution. To compete effectively in this global business environment, communities and companies will need reliable, secure access to huge amounts of data, available anytime, anywhere. However, the U.S. currently lacks the technology to ensure adequate capacity to achieve a large-scale network capable of this vision. There has been a 5,000 percent growth in demand for wireless internet data in the last three years. Currently, 3 percent of wireless smart-phone customers use up to 40 percent of the total available cell-phone bandwidth causing bottlenecks in mobile broadband access. Service providers are striving to address the rapid increase in demand, but additional technologies and

approaches are needed. Advances in broadband technology or network capacity alone will not be sufficient to meet the future needs of a hyper-connected world.

This initiative will help support continued operations of the 700 MHz Public Safety Broadband Demonstration (PSBD) Network and to make modifications to allow additional use as a platform for addressing interoperability and performance questions on non-PS next generation communications technologies. It will address three key areas to enable significant innovation in communications in both the commercial and public safety sectors. Benefits expected from funding of the advanced communications initiative include the development of a U.S. broadband network with greatly expanded capacity that requires only a marginal increase in capital and operating expenditures. In addition, it is expected to establish a testbed and build collaboration with the telecommunications industry to help lay the groundwork for an interoperable public safety communications network that seamlessly delivers voice, data, and video to first responders and other emergency personnel through whatever communication avenues are available. My company is engaged in deploying next generation 9-1-1 service in several states and has routed about half the country's wireless 9-1-1 calls for the past decade, so we are highly interested and involved in ways that technology enhancements can significantly improve public safety.

Refinement of U.S. Intellectual Property Law

I previously mentioned the 700 MHz Public Safety Broadband Network and TCS's significant position as a vendor of 9-1-1 wireless services. I am confident that every member of this committee recognizes the importance of 9-1-1 services, a vital national service that protects the lives and property of every American. Unfortunately, today 9-1-1 is threatened by what the Federal Trade Commission has termed Patent Assertion Entities, or "PAEs." The business model of PAEs focuses on purchasing and asserting patents against manufacturers already using the subject older technology, rather than the traditional and beneficial practice of developing and transferring new technology via purchased patents. PAEs have increasingly focused on the mandatory provision of 9-1-1 services by wireless carriers as proof of infringement with significant financial consequences for both the carriers and their 9-1-1 vendors, like TCS.

For the record, as the owner of over <u>200 issued</u> patents worldwide and more than 300 pending applications, TCS supports a strong intellectual property system, and we welcomed the September 2011 passage of the Leahy-Smith America Invents Act (AIA) as a watershed achievement in advancing the U.S. intellectual property system. However, the problem of PAEs and their potential to undermine our national 9-1-1 system remains. Until it is addressed, the 9-1-1 system is at risk. I strongly encourage you to investigate and resolve the PAE 9-1-1

problem before it irreparably harms America's safety and security by disrupting our national 9-1-1 system.

A Highly Skilled Work Force

In addition to supporting the research, government must also support the entrepreneurial and technological talent that brings this research to life. TechAmerica wholeheartedly supports investing to improve math and science education for U.S. students, particularly in grades K through 12. Other countries have been devoting more resources to Science, Technology, Engineering and Math (STEM) education for some time. Our understanding is that the U.S. is making strides in these areas, but we must continue our commitment to enhance the proficiency of our students in these areas.

In addition to better educating our own students, it is also critical that we ensure that the best and the brightest scientists and entrepreneurs from all over the world want to come to the United States to innovate and grow their businesses. Investors in entrepreneurial innovation have long supported immigration reform that would make it easier for highly skilled foreign born nationals to build companies in the United States.

Yet U.S. immigration policy is restrictive relative to the policies of foreign countries – while at the same time those countries are proactively growing their own entrepreneurial and innovation ecosystems. As the United States is making it more difficult for foreign scientists and entrepreneurs to enter our country, India, China and other countries are welcoming these bright minds to their shores. Unless we significantly change immigration policy for highly skilled workers, we risk losing the brightest talent to our global competitors.

For this reason, we enthusiastically support the Start Up Visa initiatives that have been introduced in both the House and the Senate. Under these bills, immigrant entrepreneurs can obtain a special visa to build their companies in the United States if they have secured venture capital financing from a qualified investor. The passage of such a bill would send a much needed signal to entrepreneurs around the world that United States wants them innovating here. Companies that are formed here drive innovation here. There is no other way to say it.

Investment in America's Small Innovative Start Up Companies

Whether it's a garage, a basement, or a dorm room, every business has humble beginnings. It's not about where you start. It's where you end up. No other industry produces more, or relies on, startups more than the technology industry. Today, 1 out of every 3 new jobs is created by self-employed startup businesses. My entrepreneur employer got started with his wife and a childhood friend. According to analysis conducted by the Ewing Marion Kauffman Foundation, companies less than 5 years old accounted for nearly all net job creation in the United States between 1980 and 2005. New firms create on average approximately 3 million jobs each year.

Encouraging early-stage investment and growth in these fast-growing, entrepreneurial start-up businesses is one of the best ways Congress can help foster an environment to create new jobs.

One of the greatest challenges facing new start-up companies is gaining access to enough capital to get off the ground in the first few years. Recent Congressional action on the JOBS Act is a positive step in addressing the regulatory burdens small companies face in their efforts to go public. The JOBS Act will encourage and promote economic growth by making it easier for emerging growth companies to access capital and by easing the Initial Public Offering ("IPO") process for these companies. In particular, by providing an "on-ramp" to the public markets, the JOBS Act will provide emerging growth companies with relief from some compliance requirements that are particularly challenging and costly for small companies. A critical step in growing our company was our IPO 12 years ago, and we now employ about 5 times the 295 employees in our 2000 prospectus. We were very fortunate to raise our capital shortly before changes in the environment sharply changed access to such capital for similar stage companies since then.

TechAmerica also supports S. 1965, the Startup Act, introduced by Senator Mark Warner (D-VA) and Senator Jerry Moran (R-KS). This legislation would further address the challenges faced by American startup companies. In 2010, Congress temporarily exempted capital gains taxes on the sale of certain small-business stock held for at least five years. The Startup Act would make this exemption permanent, giving investors an incentive to partner with entrepreneurs and provide financial stability at a critical juncture of firm growth.

To further encourage business development, the Startup Act also reduces the corporate income tax on certain new businesses during the first three taxable years of profit. To fuel access to

capital, the Startup Act would examine whether or not Sarbanes-Oxley compliance could be eased for small issuers, potentially allowing the market to weigh the costs and benefits.

Another significant obstacle facing new businesses is the expense and time required to comply with government regulations. According to the Small Business Administration, firms with fewer than 20 employees spend 36 percent more per employee than larger firms to comply with federal regulations. This legislation requires all government agencies to conduct a cost-benefit analysis of all proposed new regulations with an economic impact of \$100 million or more. This analysis will determine the efficacy of the rule and its potential effects on the formation and growth of new businesses.

The Startup Act will help keep entrepreneurial talent and highly skilled workers in the U.S. by establishing a new category of visas for immigrant entrepreneurs. It also creates a pathway for foreign students who graduate from an American university with a master's or Ph.D. in science, technology, engineering or mathematics to receive a green card along with their diplomas so they can stay in this country, launch businesses, and create jobs.

We encourage the Members of the Committee to introduce a House companion measure.

Providing Greater Market Access for U.S. Technology Businesses

The U.S. high-tech industry and the 5.9 million workers that it employs rely on international trade and investment for continued growth, innovation, and job creation. Engaging in international trade buoys GDP growth, enhances productivity, and boosts the ability of small businesses to innovate and create good, U.S.-based jobs.

During the past two years of economic distress, exports have helped to keep the economy afloat. High-tech exports grew 38 percent from 2002 to 2008, according to TechAmerica Foundation's *Trade in the CyberStates 2010 Report*. These technology exports supported 1 million U.S. jobs in 2009. In addition, U.S. high-tech exports were the largest overseas exports in 2009 totaling \$188 billion.

High tech accounts for nearly a quarter of all exporting small businesses, and in 2007, 94 percent of the companies exporting high-tech goods were small companies with less than 500 employees. And the role of small businesses in this area has been increasing. My company is currently deploying our wireless network technology in emerging market carriers in Latin America and Africa.

TechAmerica has been supportive of efforts by the Obama Administration to advance the Trans-Pacific Partnership (TPP) regional trade agreement. The TPP comprises the United States, Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore and Vietnam. These countries represent about 26 percent of global GDP and approximately 17 percent of world trade. The agreement will underpin the rules for international trade and investment in the region for years to come. Ten rounds of negotiations of the TPP agreement were held in 2011, with additional rounds scheduled for 2012. TechAmerica is an active member of the High Tech Trade Coalition which is monitoring those negotiations. TechAmerica supports new countries joining TPP with participants complying with current international norms and obligations, and committing to the high standards currently being negotiated for trade and investment, as well as intellectual property protection and enforcement, building upon the IP Chapter in the US-Korea FTA.

At the same time that the United States is seeking to press foreign governments to open their markets and eliminate barriers to trade, we need to look at U.S. policies that could help small businesses grow their exports.

Small technology companies are generally not equipped to deal with the complexities of the export controls and can be discouraged from exporting by the risks of not properly complying with the rules. We are encouraged by the steps of the Obama Administration to finally move forward with changes that we hope will address these concerns and are working with members of Congress on updated legislation.

Small businesses seeking to export to foreign markets must grapple with finding reliable business partners in other countries, navigating local laws and cultures, understanding the market for their products or services and working out financial issues. We recognize that there are many programs designed to help small businesses but feel that more can be done and better funding can be provided to strengthen the programs aimed at helping U.S. small businesses export their goods and services.

Small business innovation and new firm formation help ensure U.S. products and services remain at the cutting edge. Enforcing existing and pursuing new free trade agreements brings down barriers to entry for the goods and services of small businesses and allows them to market themselves to new consumers around the world.

Conclusion

The United States has harnessed innovation to power economic growth, raise standards of living and enhance the quality of our standard of living. The federal government has played an indispensable role in this success through innovation-friendly policies and incentives. We commend those in Congress who seek to foster an ecosystem where risk taking and entrepreneurship are rewarded. Yet the bar continues to rise as many foreign governments have begun to emulate our success and seek to surpass it. Their successes mean that we no longer hold a monopoly on innovation and its benefits. Standing pat means falling behind.

Make no mistake: The race is still ours to lose. But to maintain our innovation advantage, we must rededicate ourselves to what made us successful: increasing support for basic R&D, improving math and science education, supporting immigration and opening new markets, and improving access to capital through smart tax policies. Without action on these fronts, the United States may find itself in the unfamiliar role of also-ran in the innovation race. The technology industry remains committed to doing our part to ensure this is not the case.

TechAmerica looks forward to working with members of this committee, Congress and the Administration to support the best and brightest ideas and continue to fill a robust pipeline of innovation for our country.

I thank the Committee for the opportunity to discuss these important issues with you today and I am happy to answer any questions.

Chairman QUAYLE. Thank you, Mr. Brandt. I now recognize our final witness, Mr. Richard Bendis, for his testimony.

STATEMENT OF MR. RICHARD BENDIS, INTERIM CEO, BIOHEALTH INNOVATION, INC., AND PRESIDENT AND CEO, INNOVATION AMERICA

Mr. Bendis. Thank you, Mr. Chairman. Chairman Quayle, and Ranking Member Edwards-

Chairman QUAYLE. Is your mic on?
Mr. BENDIS. Thank you for the opportunity to testify before the Committee today. My name is Rich Bendis, and I am President and CEO of BioHealth Innovation, Inc. It is a private-public partner-ship that is predominantly funded by the private sector to foster biohealth innovation-based economic development and is a unique cluster-based model for regional economic development. This initiative could be used as a model program regardless of industry or

cluster strength.

BHI is the first regionally focused innovation intermediary created to connect the university and hospital biohealth research strengths of Baltimore with the bioscience industry and federal laboratory strengths of Montgomery County. It has entered into a Partnership Intermediary Agreement with the National Institutes of Health's Office of Technology Transfer and has created the first private-sector funded Entrepreneur in Residence program to identify commercializable science in the 27 institutes of NIH. This program will create new project-based companies and high-paying life science jobs. BHI believes this EIR program is applicable to many federal agencies that have technology transfer offices and support SBIR programs.

BHI has designed a potential national pilot, the Health-Regional Innovation Cluster, H-RIC, model, which will incorporate the best innovation-based economic development practices in the United States and integrate them into one region in Central Maryland. BHI is currently seeking federal financial support from several relevant federal agency partners to accelerate the creation and imple-

mentation of this innovative biohealth H-RIC model.

Over the past 35 years, I have developed and led innovationbased technology organizations in Kansas, Pennsylvania, and currently in Maryland. I also worked as consultant in many States and countries to help them with their programs. For example, Iowa's Innovation Council was the recipient of the Economic Development Agency, EDA's, 2011 i6 Proof of Concept Challenge Grant, and Innovation Philadelphia was the recipient of multiple grant awards by EDA's Public Works Grant program. These grants enabled the innovation-based strategies to be successfully developed and implemented within these States and regions.

I have also partnered and served as a member of the United States Innovation Partnership, which was formed by the Technology Administration of the U.S. Department of Commerce under

the Clinton Administration.

The America Competes Reauthorization Act of 2010 established the Office of Innovation and Entrepreneurship with its National Advisory Committee on Innovation and Entrepreneurship, and this was created to serve as the central location and focal point for these activities to foster interagency cooperation. I believe this should remain a priority for the U.S. Government, but it needs to have higher Administration and congressional visibility and empowerment to lead the innovation strategy for the Federal Government and America.

The Department of Commerce and EDA should still continue to lead this initiative, but it needs a senior official who is empowered, fully budgeted and staffed office with clear responsibilities, and measurable outcomes. An earlier version of this office was created as the Technology Administration Office within the Department of Commerce under the Clinton Administration and had Undersecretary Dr. Mary Good leading the office. It was the closest we came to having an empowered technology and innovation coordinating body for the Federal Government.

Today's theme, "Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth," needs to commence at the regional level where job creation occurs. It needs to link the economically distressed regions together with stronger regions to develop the much-needed jobs from the laboratories to the market, similar to the i6 program that EDA had created. EDA and the Department of Commerce need additional flexibility in their program design and implementation, as every region in the United States has their unique assets, strengths and needs.

There are several positive programs that affect the federal policies on competition, innovation, and job growth. The following are examples that have helped mitigate the risk of those companies facing the valley of death in commercialization or capital.

Number one, I applaud the SBIR reauthorization, but there is a need for a Phase III commercialization award category, especially in high-capital industries such as biotechnology and energy that require extensive R&D investment.

Second, the National Institutes of Standards, NIST, Technology Innovation Program, TIP, was effective and was not corporate welfare as perceived, since it brought together large and small companies and universities to tackle high-risk mission-critical technology innovation projects that no other federal program addressed. TIP needs to be reinstated because it fills a critical gap in the innovation funding continuum.

Continued support and growth of the Manufacturing Extension Partnership, MEP, is an excellent example of how the Federal Government, States and the private sector can all work together to tackle major challenges in our economy, especially in manufacturing.

We need to create an early-stage seed jobs fund—of—funds to address the innovation capital valley of death that would complement the expanded Small Business Investment Company, SBIC, program that has really taken off this year.

A national angel capital credit program to stimulate private early-stage investment in high-risk, early-stage ventures funded by private individuals is also something that America needs to create. Thirty States have programs with angel capital tax credit programs today.

I agree with the permanent reauthorization of R&D tax credit, and we should also add a transferability component to the R&D tax

Lastly, we need an expansion of the Treasury program, New Markets Tax Credit, for venture capital investment, especially in early-stage companies and an expansion of the new State Small Business Credit Initiative, SSBCI, that would increase the percentage of allocation to seed and early-stage venture capital.

Thank you much for the ability to make this testimony, and we will stand for questions now. Thank you.

[The prepared statement of Mr. Bendis follows:]

PREPARED STATEMENT OF MR. RICHARD BENDIS

Statement of

Richard A. Bendis

Before the House Science, Space and Technology

Subcommittee on Technology and Innovation entitled,

"Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth"

March 27, 2012

Presented by:

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Testimony before the House Science, Space and Technology Committee's

Subcommittee on Technology and Innovation

Entitled

"Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth."

Presented by:

Richard A. Bendis

President and CEO BioHealth Innovation Inc. Founder of Innovation America Publisher of InnovationDaily

Chairman Quayle and Ranking Member Edwards, thank you for the opportunity to testify before the House Science, Space and Technology Committee's Subcommittee on Technology and Innovation on the important topic of "Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth."

My name is Richard Bendis and I am the President and CEO of BioHealth Innovation Inc., (BHI). BHI is a private-public partnership that is predominantly funded by the private sector to foster biohealth innovation-based economic development, which is a unique cluster-based model for regional economic development. This initiative could be used as a model program regardless of industry or cluster strength.

BHI is the first regionally focused innovation intermediary created to connect the university and hospital biohealth research strengths of Baltimore with the bioscience industry and federal laboratory strengths of Montgomery County. It has entered into a Partnership Intermediary Agreement with the National Institutes of Health's Office of Technology Transfer and has created the first private-sector funded Entrepreneur in Residence (EIR) program to identify commercializable science in the 27 institutes of NIH. This program will create new project-based companies and high-paying life science jobs. BHI believes this EIR program is applicable to many federal agencies that have technology transfer offices and support SBIR programs.

BHI has designed a potential national pilot, the Health-Regional Innovation Cluster (H-RIC) model, which will incorporate the best innovation-based economic development practices in the United States and integrate them into one region in Central Maryland. BHI is currently seeking federal financial support from several relevant federal agency partners to accelerate the creation and implemention of this innovative biohealth H-RIC model.

As the founder of Innovation America, I publish innovationDAILY, a daily electronic newsletter on the pulse of global innovation, entrepreneurship, angel/seed and venture capital and innovation-based economic development. InnovationDAILY has over 1,000,000 unique visitors in over 185 countries.

Over the past 35 years I have developed and led innovation and technology-based economic development organizations in Kansas, Pennsylvania, and currently in Maryland. I have also performed successful consulting engagements including a recent engagement with the state of Iowa's Innovation Council and with over 30 cities, regions, states, and countries. These projects advanced innovation-based polices and programs to grow the economies of their respective locations. The projects identified the assets of each geographical region, the leadership of the stakeholder organizations and developed implementation strategies.

For example, the Iowa Innovation Council, which was a recipient of the Economic Development Agency (EDA)'s 2011 i6 Proof of Concept Challenge Grant and Innovation Philadelphia was the recipient of multiple grant awards by EDA's Public Works Grant program. The funding was provided by EDA on both of these engagements, which enabled the innovation-based strategies to be successfully developed and implemented.

As a founding board member of both the State Science Technology Institute and the National Association of Seed and Venture Funds, I understand the organizational needs of seed and early-stage venture capital that is deployed to emerging technology companies. I also have had the opportunity to serve as a member of the United States Innovation Partnership, which was formed by the Technology Administration of the U. S. Department of Commerce under the Clinton Administration.

Competing globally today, the United States needs to develop a national innovation strategy that leverages federal assets and programs with regional academic, industry and non-governmental organizations. More importantly, the strategy needs an implementation plan and leadership group to make certain America regains its innovation leadership and strengthens its position for the future. The America Competes Reauthorization Act of 2010 established the Office of Innovation and Entrepreneurship with its National Advisory Committee on Innovation and Entrepreneurship, which was created to serve as the central location and focal point for these activities and to foster interagency cooperation. I believe this should remain a priority for the U.S. Government, but it needs to have higher Administration and Congressional visibility and empowerment to lead the innovation strategy for the federal government.

The Department of Commerce and EDA should still continue to lead this initiative. But it needs a senior official in an empowered, fully budgeted and staffed office with clear responsibilities and measurable outcomes. An earlier version of this office was created as the Technology Administration Office within the Department of

Commerce under the Clinton Administration and had Undersecretary, Dr. Mary Good, leading the office. It was the closest we came to having an empowered technology and innovation coordinating body for the federal government. The recent Jobs Act provides more instruments like Crowdfunding, which was strongly supported by most innovation-based entrepreneurial organizations. The passing of the Act will enable more small companies to develop the capital they need to grow.

Today's theme, "Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth." needs to commence at the regional level where job creation occurs. The regional strategy needs support from state-based funding programs and federal programs to leverage private-sector resources and knowledge. These functions support the commercialization of the intellectual properties being developed by university and federal research institutions, entrepreneurs and incubators. The U.S. DOC/EDA needs increased appropriations to support and stimulate regional innovation strategies. It needs to link the economically distressed regions together with the stronger regions to develop the much-needed jobs from the laboratories to the market. They also need additional flexibility in program design and implementation as every region in the U.S. has their unique assets, strengths and needs.

BHI has developed a vision for a national pilot, the Health –Regional Innovation Cluster. President Obama's Memorandum, "Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses" directed federal agencies to develop plans that establish performance goals to increase the number and pace of effective technology transfer and commercialization activities in partnership with private firms, research organizations and nonprofit entities. BHI is an organization that will fulfill and manage this directive as a regional pilot program with the ability to replicate the biohealth innovation intermediary model nationally.

There are several positive programs that affect the *Federal Policies on Competition, Innovation, and Job Growth.*" The following are examples that have helped mitigate the risk of those companies facing the Valley of Death in Commercialization or Capital:

- 1. SBIR reauthorization There is a need for a Phase III commercialization award category, especially in high capital industries such as biotechnology and energy that require extensive R&D investment to be successfully commercialized. The U.S. SBIR program is the best in the world that many replicate and we need to continue to maintain it to keep our competitive advantage in innovation.
- The National Institutes of Standards and Technology's (NIST) Technology Innovation Program (TIP) program was effective and was not corporate welfare as perceived, since it brought together large and small companies and universities to tackle high-risk, mission-critical technology innovation

- projects that no other federal program addressed. TIP needs to be reinstated because it fills a critical gap in the innovation funding continuum.
- 3. Continued support and growth of the Manufacturing Extension Partnership Program (MEP), which is an excellent example of how the federal government, states and the private sector can all work together to tackle major challenges to our economy.
- 4. An early-stage seed jobs "fund of funds" to address the innovation capital valley of death and would complement the expanded Small Business Investment Company (SBIC) program.
- 5. A national angel capital tax credit program to stimulate private early stage investment in high risk, early stage ventures.
- 6. Permanent reauthorization of R&D tax credit and adding a transferability component.
- 7. Expansion of the New Markets Tax Credit program for venture capital investment.
- 8. Expansion of the State Small Business Credit Initiative that would increase the percentage of allocation to seed and early-stage venture capital.

In summary, we need to identify innovation ecosystem gaps where the federal government can play a role and design private-public partnership programs to leverage industry and the private sector resources. The Department of Commerce (DOC), NIST and EDA are effective agencies that need additional resources to fill the gaps in the innovation program portfolio to create and support an integrated national innovation strategy that engages all stakeholders.

America has the assets, leadership and innovation capability to develop a long-term strategic innovation plan that leverages all stakeholder resources, encourages collaboration, reduces redundancy and restructures our federal programs to maximize return on investment. We simply cannot afford the alternative.

Thank you.

Chairman QUAYLE. Thank you, Mr. Bendis, and I would like to thank all of our witnesses for their testimony today.

Reminding Members, the Committee rules limit questioning to five minutes. The Chair at this point will open the round of ques-

tions, and I will recognize myself for five minutes.

Mr. Truitt, within your testimony you stated that there is absolutely no doubt that tax policy, both the burden and the uncertainty, impacts competitiveness. This includes uncertainty with the R&D tax credit as well as tax rate increases. In fact, there are over about 200 federal tax provisions that are scheduled to expire between 2010 and 2020. These policies really affect the ability for businesses to grow with research projects that are budgeted and planned for a three- to five-year basis. How does uncertainty really reduce the ability to map out a business plan for future innovation and investment?

Mr. TRUITT. I am not really a tax expert, but what I can tell you is that we always have to look at what resources we have available, both in people and in money, when we look at how our map goes forward and how we produce or develop new products. When we do that, you know, a new product that may have some real research to it, instead of just development to it, where we have to go in and take some real risk to it, we may not be able to take that risk if we don't have this R&D tax credit to go along with it.

Chairman QUAYLE. Okay. Thank you. And Mr. Brandt, kind of along those same lines, there has been a lot of talk about simplifying the tax code, especially on the corporate side, reducing the number of deductions and tax credit within the system to get a lower rate. Would you be willing to give up something like the

R&D tax credit for a lower rate at the corporate level?

Mr. Brandt. Well, speaking for myself and as a financial officer, certainly the cost of compliance with the complex code helps to offset the benefits of something like the R&D credit. The R&D credit is somewhat focused insofar as being an incentive for technology innovative companies to have a little bit more resources than they otherwise would to reinvest in development activities they wouldn't otherwise have the funds for.

So I happen to be a big advocate for greater simplicity, speaking as a guy who has to ensure those forms get completed accurately

and has to sign them.

Chairman QUAYLE. Yes, we want to make your job easier. But true to course, I think there is, you know, broad agreement on both sides of the aisle on the importance of government-supported basic research. However, I do get concerned about excessive technology transfer funding by the Federal Government that can lend itself to picking winners and losers.

What do you view, Mr. Brandt, as the appropriate use of federal

funding versus industry funding in tech transfer programs?

Mr. Brandt. My observation is they are symbiotic. My company in part owes its legacy to DARPA and the investments that went into enabling the Internet and the connectivity that has then in turn led to the wireless industry and the broadband technology that benefits society in a lot of ways. So I like to think it is not an "or" but an "and," and I am sure there is lots of judgment as to where the balance is. But I see benefits from both.

Chairman QUAYLE. Dr. Cohen, do you have any thoughts on where it lies within tech transfer, whether on the federal involve-

ment versus the private sector involvement?

Dr. Cohen. It is a combination, as I think we are hearing from the other witnesses. Clearly, I believe most of the drive, the innovation, and the funding has to come from the private sector, but there is a time when having a kick start or a balance provided from government funding can be very helpful. In the case of my company, which I started out of my bedroom, you know it is now valued at \$1 billion and, as I said, employs over 330 people and gives additional help to thousands of other people that we interact with in terms of their jobs and employment.

But in the early days, it was very difficult to raise funding. It always is in an early startup. And we managed to get some SBIR grants. Back then there was the ATP or the Advanced Technology Program grants. We got a \$2 million grant, which was a competitive grant that was adjudicated by a panel of experts based on the information we provided. That actually we were able to translate into enormous progress that then enabled us to raise a \$20 million

private venture capital round.

So there really is a place where, especially in the R&D phase, when it is so difficult to kick start things that ultimately may become real contributors to the economy, real contributors to our health and so on. There is a place where the right sort of incentives can be the difference between life and death for these companies.

Chairman QUAYLE. Great. Thank you very much. I now recognize

Ms. Edwards for five minutes.

Ms. EDWARDS. Thank you, gentlemen, for your testimony. I want to stay focused on that because although I have, you know, an interest in a lot of our tax policy, too, I have my own R&D tax credit bill, this Committee has really limited jurisdiction. So I want to focus on the things that we on our Committee could potentially do something about because otherwise, it is just kind of an abstract conversation.

So, Mr. Bendis, in your testimony, you talked about the Technology Innovation Program, and what I would like you to focus on are some of the gaps that you mentioned where, you know, TIP fills important and critical gaps, but now, because of congressional action, we really don't have the benefit of that. And also if you could give me an idea about your perceptions of the predecessor program, the ATP, program as well.

Mr. Bendis. Yes, Congresswoman Edwards, I believe the U.S. Government and Congress could take a look at a gap analysis, and to be honest with you, the gaps are wider and deeper than they have ever been in the private sector because venture capitalists are

moving upstream and funding less early-stage capital.

So I don't believe the Federal Government should fund by itself every different segment and stage of the life cycle within a company, but there are appropriate roles that the Federal Government

can play. I will start at the beginning of the portfolio.

The SBIR program is the best program in the world for doing early-stage funding. Many countries have copied what we do in the United States, and I couldn't believe that we had to go through so many reauthorization challenges here to get it reauthorized. It is

something that also should become permanent in this government because it is the best early-stage investment program that America has, and we should not have to go through the reauthorization

process, even after six years.

As I mentioned in my testimony, where we have a tremendous gap in the innovation capital area right now is in commercialization, and basically bridging the gap from proof of concept to what I classify as proof of commercial relevance is where Phase III would empower people to get their technologies, to get it market and com-

mercial ready.

On the TIP program, it was designed to deal with mission-critical, federal agency, mission-critical, and Federal Government and America mission-critical technologies in areas that needed to be focused on to enhance the quality of life, our infrastructure and defense of the United States. Since that program has been discontinued, there basically isn't a program to replace it with federal funding, and companies generally don't have the capital to take on this high-risk research themselves.

The difference in the ATP program and TIP program was ATP tended to be more focused on large companies, but the TIP program organized itself to focus on partnerships with small business, academic institutions and large business but was predominantly small-business oriented, where basically that research should

begin.

Ms. EDWARDS. Thank you, Mr. Bendis. And let me just interrupt you because I think it is important for us, and I want to hear from each of you just very briefly. Is there universal agreement across this panel about the benefit of the SBIR program? Mr. Truitt?

Mr. TRUITT. You know, there was for us, you know. We have gone to a point now where it is beyond what Ludlum works with, but I could see where in the future that start-up companies need something like that.

Ms. EDWARDS. But when you started up, you, your company, as I understand it, has had the benefit of SBIR. Am I correct? So it was important for beginning, even though for companies that are well down the line, it may not be as valuable as those start-ups, is that right?

Mr. TRUITT. Yes, that is true. And when we started up, we did have the benefit of, you know, the SBIR, and the local bankers and things that were—again, back then, you know, handshakes meant something. And that is really how a lot of the business was done.

Ms. EDWARDS. Mr. Brandt.

Mr. Brandt. And I can report that our company benefited from the 8(a) program early in its life, and at the time we did our IPO, the pure venture money was supplemented and enhanced by an SBIC. So those were key milestones in the development of our

1,500 person company.

Ms. EDWARDS. Thanks, and I appreciate that because I think sometimes we get confused. I mean, there is an important role, especially in a start-up for several different programs, whether it is through SBA, SBIR, you know, these things that really can sort of jump start without choosing winners and losers. That is not what this is about, but it is saying, you know, there are some ideas out there that have to be seeded. The Federal Government can provide

some of that seed, and then you all go off and let your thousand flowers bloom without us choosing which one of them are the ones

that should be picked. And with that, I think I will yield.

Mrs. BIGGERT [presiding]. Thank you, and I would now yield myself for five minutes. Mr. Brandt, thank you so much for what you do for TechAmerica. I think that is so, so important to our country. You know, we have heard a lot from companies about the time and resources required to comply with the regulations. In fact, some of them say that the only job they have been able to hire for has been compliance officers. So I think that that shows that there is a problem here.

Can you give us a sense of cost and time required by your com-

pany to achieve regulatory compliance?

Mr. Brandt. Well, what is closest to my desk is Securities and Exchange Commission requirements for being a public company, and the cost and time certainly went up a notch as the Sarbanes-Oxley 404 rules kicked in, and we have been obliged to invest for internal control, monitoring and reporting, at a much higher cost than prevailed before that rule came into effect.

Mrs. BIGGERT. Does it really affect your business and investment

decisions?

Mr. Brandt. Well, it diminishes the capital that is available to invest elsewhere. So to the extent I have an internal audit department now and I have staff that are virtually full time committed to ensuring that we have records of having checked ourselves multiple times during the year for compliance with our own policies. Those are dollars that are not available for us to hire engineers to enhance our products and be more competitive.

Mrs. BIGGERT. The SEC I think has at least 450 regulations that they are working on or have already brought forward. Are a lot of

these the ones that you are working on?

Mr. Brandt. Well, between the outside auditors and the attorneys who are, on the average, \$300 to \$500 an hour, they monitor all those rules on behalf of my office and the company, and I am sure they all factor into those bills.

Mrs. BIGGERT. Thank you. Then, Mr. Truitt, you testified that trade policies affect the cost of doing business for companies in the global markets, and you cite policies and partnerships critical to the U.S. competitiveness and economic growth. How can the United States best promote exports through trade agreements, and can you give us a sense of how access to new markets enable small-and medium-sized enterprises to create jobs and grow their businesses?

Mr. Truitt. Yes, trade agreements do play a big part in what we can do. The recent trade agreements with South Korea, which has a big nuclear industry, and in fact, they are building nuclear power plants for other countries now, has made it so that we are more competitive with local companies because there are local companies within South Korea that compete with us. So it makes it so we are on a more level playing platform. More trade agreements like this, because most countries around the world have more than what the United States do, would certainly make us more competitive in more countries.

Mrs. BIGGERT. It seems like those trade agreements that we have just had with South Korea and Panama and Colombia really took a long time to get out.

Does anyone else have anything they would like to add to that

question? Anybody else deal with trade? Okay.

Let me go back to research and development. It seems like research and development is so important that we have the Office of Science for the Department of Energy and Department of Defense does a lot of this. But you talked about the valley of death that so many companies reach. And I have had a couple of companies that have come to me and, you know, they have a product, it works but they can't get to that part where they can really, you know, open up a big shop. What do we do with them? There is one right now that really is an important issue that could really solve some of the problems that we are having with gasoline and diesel. Anybody have any ideas? Mr. Bendis.

Mr. BENDIS. Yes, ma'am. Basically, every company shouldn't create a big shop. What we need to determine whether or not is whether they have something that is commercially relevant, that somebody wants to buy and that there is a scalable market to be able to create a real business around it. So what we can do to them is to mentor them, provide advice to them initially, not give them money, but I think they need knowledge more than they do money sometimes to determine whether or not the market really needs

their technology.

And the other thing is there are a lot of State resources that exist in each of the individual States, and that means that if, for example, in Maryland you have TEDCO, which is a tech-based economic development organization, that can provide some support to them. Some of the tech transfer offices can also provide some support to them.

So at the end of the day, I think providing good mentoring knowledge and access to resources might be one of the best things that could be done for these companies and entrepreneurs.

Mrs. BIGGERT. Thank you very much. Dr. Cohen.

Dr. Cohen. Yes, speaking for the biotechnology industry, one of the key issues in allowing that sort of growth and transition for us is now the regulatory pathway, and we are one of the most regulated industries in the world, and rightly so. People need to be assured that we have safe and effective medicines, and that is what the FDA tries to do.

But the reality is over the last decade or so, the pathway has become so burdensome that the timelines have been increasing, and companies are finding it harder and harder to get their products to market, even with drugs that work and can confer benefits. So, for example, in 2001, drugs that got approved on average had taken about 12.4 years or so to get through the development process. Now it is about 14.8 years. So in just 10 years, we have increased the burden by over two years, and that seems to be continuing.

So things that can be done, for example, what I suggested in my testimony are approval of bills like the FAST bill where we can get pathways adopted by the FDA and expand them to many diseases that are serious, that require answers. Right now those pathways

are being applied reasonably well in HIV and cancers. But for other diseases that are equally serious or sometimes more so, they are not being applied. And that is a critical thing that could help the biotech industry because investors have recognized this, and 61 percent of venture capitalists in a poll last year cited the regulatory uncertainties as the reason that they are reducing their investment in the biotechnology industry.

Mrs. BIGGERT. Thank you very much, and I have gone over my time, but now I recognize the gentlelady from Oregon, Ms.

Bonamici.

Ms. Bonamici. Thank you very much, Madam Chair. Dr. Cohen, you just anticipated and answered my question. But I wanted to follow up a little bit about it because you talked about this FDA approval process in your testimony, and it is something that I have heard about from constituents, both relating to drugs and devices, and you did mention that one of the reasons why there is reduced investment in medical science sectors is because of this regulatory challenge. I think we can all agree that we need to have a process to assure that the drugs and the products are safe.

So can you expand a little bit about the FAST bill, and I know there is already the accelerated approval. What else can be done so that we can assure safety but speed up the approval process?

Dr. Cohen. So thank you for the opportunity to respond to that. There are a number of things that can be done to respond to that particular issue, and in my view it is the leading issue for the biotech industry in terms of what could be done to foster the industry and make sure that it is healthy and growing and helping all of us.

BIO has put forth a series of suggestions, so for example, in the FDA's mission statement, right now it does not include a commitment to foster biomedical innovation. We think it should, because out of that will flow a decision-making process that will take into account that, for example, there is a cost not only to putting a potentially unsafe drug on the market, but there are many costs to not putting a potentially effective drug on the market in a timely way. And too often in that equation, that part of it is not given due weight.

So what is the cost to patients who need a drug now of not getting it to them now, versus the cost, of course, you don't want to get an unsafe drug out there.

But the balance is in my view skewed on one side, and it needs to have that other balance, on behalf of the patients who need the drugs. The patients' voices themselves are too often not included in the process. There ought to be more ways for patient groups to make their voices heard in terms of what do they consider a benefit to them, and what do they consider a risk that they are willing to assume. That voice is too often missing from the equation.

So there are many different things. There are others—in my written testimony I think we have a longer series of proposals—but a very good start is embodied in the FAST Act. It includes some of what I have just talked about, but in particular this issue of accelerated approval, which is an existing pathway.

Ms. Bonamici. Right.

Dr. Cohen. The FDA already recognizes it, but it is not sufficiently broad in its application. There is not sufficient transparency to companies like mine where we can have a dialogue with FDA and say, well, do we potentially qualify for this pathway? And over all, there needs to be more transparency and communication between drug sponsors, like my company, and the FDA. And one of the encouraging signs in the PDUFA legislation that is up for reauthorization is FDA did agree to an ombudsman that would now help facilitate basic communications back and forth, where now if my group has a simple question that could be answered theoretically in a day or two, it could take a few months before we get our answer. And during those few months, we are paralyzed. We can no longer continue with our development program.

So these are the sorts of things that I would be very happy if Congress would continue to focus on to help the FDA accomplish the mission that they want to accomplish which will help all of us.

Ms. Bonamici. Terrific. Thank you very much. Mr. Truitt and Mr. Brandt, thank you for your testimony as well. I know you both mentioned the difficulty of finding highly skilled, qualified workers. And I suspect as we move toward more advanced manufacturing, that difficulty is going to grow. And Mr. Truitt, I understand you are here on behalf of the Chamber, and I want to applaud you for talking about the need for high-skilled immigration reform and how it needs to be coupled with education reform. I think I couldn't agree with you more on that.

But putting aside the immigration issue, what else can we do as government policymakers to improve the training of our domestic workforce to meet these growing advanced manufacturing needs?

Mr. BENDIS. I believe that continued support for STEM is extremely important and also looking for advanced workers. All of them don't need to have graduate degrees. I think the community colleges in America play a tremendous role in providing skilled workers, and I think they can actually help support the need for skilled workers as our advanced manufacturing needs occur because everybody doesn't need to be a Ph.D. or scientist. But I think also some of the major professional societies in America and associations need to work on this problem because it is not just a congressional or a federal problem. I think it is an industry problem which a lot of them are trying to address as well as to how do we increase the quality of our workforce in America to be able to compete on a global basis.

Ms. Bonamici. Thank you very much, and I believe my time is expired. Thank you.

Mrs. BIGGERT. Thank you. The gentleman from Illinois, Mr. Li-

pinski, is recognized for five minutes.

Mr. LIPINSKI. Thank you, Madam Chairwoman. I have a couple questions here. First I want to thank everyone for their testimony here. Clearly we are all interested in what we can do to foster the competitive edge that our country has as our economy continues to struggle and people are asking the question. I keep saying this, although I don't think people want to voice it. Americans are saying where are our jobs going to come from, and I think certainly innovation is what we need to look to. On this Committee, one thing I want to especially focus on, and we have been focusing on, is

ways of leveraging the Federal Government's investment in basic research to spur the creation of new jobs.

If you are looking at this from an SBIR perspective, you could consider it to be Phase 0. We are talking about we have all these researchers in our universities, our national labs, who are doing all this great research, but they don't know how to start the process even trying to develop a product from that research that can create

a new company, new jobs.

Now, a couple of things we have done, the National Science Foundation has started a program called the Innovation Corps, or I–Corps, where research grant recipients can take what amounts to an entrepreneur course for scientists. In part, the corps teaches academic researchers how to develop a business model, solicit customer feedback and revise their products over and over to meet customer demands. This is based on decades of experience by entrepreneurs and venture capitalists in Silicon Valley. NSF has gone through one round of this so far and is about to do a couple more rounds of this. So it is open to anyone who has received an NSF grant.

On the SBIR side, I was able to get language into the reauthorization bill that redirects \$10 million of NIH's STTR funds for grants to universities and other research institutions to support proof of concept capabilities for researchers, that is, programs that help researchers that are attempting to found companies assess the marketability of the innovation and give them the tools they need to succeed in business. This is based on programs such as the one at University of Virginia, which has generated a five-to-one overall return on investment and new follow-on funding and a 42-to-1 ROI for the top 10 percent of portfolio projects at UVA.

So we have these two programs. I wanted to ask, first start with Mr. Bendis and then if anyone else has any comments, on I-Corps, on essentially Phase 0, SBIR over at NIH. Are these good programs? Is there anything else you would recommend for this space, for what we can do to better get the great research being done into

new products, new jobs?

Mr. Bendis. The answer, both of them are good products, Congressman Lipinski. The I-Corps I think is an innovative way that we can look at identifying some potential scientists that have ideas that may be commercializable but we can get in the marketplace

and find a way to give them some training.

Phase 0 is an extremely important part of the overall SBIR portfolio of programs, and it is a good jumpstart program to look at true proof of concept. But if we look at ways that we want to improve these programs, or look at other programs to strengthen it, and I think prior to your coming in, we talked about the Phase III commercialization program for SBIR, of which we are strong proponents and believe there is a tremendous gap that needs to be addressed there.

Second, the tech transfer offices in the federal labs generally are reactive, not proactive. That means that they basically do laboratory push with trying to push technology into the marketplace and rather than a market pull. What we have created is a very innovative program called an Entrepreneur in Residence program where we are placing a serial entrepreneur within the Office of Technology.

nology Transfer at NIH to be able to determine what industry's needs are and the market needs are today, rather than just identifying what good science is. We need to work hand in hand with these tech transfer offices from a market perspective, rather than just purely from a science and a laboratory perspective. And I

think that is a tremendous program.

Another program that is innovative in Maryland is called Innovate, and it is a program between the University of Maryland-Baltimore and Johns Hopkins where they take post-docs that have ideas, that have potential commercialization, and they work with them on a 12-month basis and educate them, basically, to determine whether or not they should be entrepreneurs, whether or not they have the capability to be an entrepreneur, or whether or not the idea is marketable. If they are not qualified at the end of that period, and say we don't want any part of entrepreneurship but the technology is good, it helps match up the technologies with potential entrepreneurs who can take it further.

But everybody that is a scientist should not be a potential entrepreneur or develop a product. And we need to have balance in our research to where we have the advancement of knowledge, which is extremely important, to our congressional and the federal mission, but at the same time identify the low-hanging fruit where there is significant commercial potential and match them up with the resources, knowledge, and the potential capital that is necessary. And there are some good programs within the Federal Gov-

ernment to support that.

Mr. LIPINSKI. Thank you, Mr. Bendis, for bringing those forward. Mr. Brandt.

Mr. Brandt. If I may, I would submit that in recent years it is not only at the gestation stage but at the adolescent and maturation stage where we have seen a big change in the reduction and venture-backed initiatives that make their way through to the stage of going public. And in order for the venture community to be as effective as it once was in filtering through the ideas and commercial opportunities that began in the incubators or in academia, they need to know where there is an exit. And today they can sell to a bigger company which ordinarily means the departure of the entrepreneur. They don't have an exit, and that has sharply reduced, it appears, their number of investments that are nurturing and bringing companies up to a larger stage where they are employing and growing more people. But the high cost of being a public company and other obstacles to going public have very, very sharply reduced the number of IPOs and consequently the middlestage companies that prevailed a few years ago.

Mr. LIPINSKI. Thank you. I yield back.

Mrs. BIGGERT. The gentleman yields back. The gentleman from California, Mr. Rohrabacher, is recognized for five minutes.

Mr. ROHRABACHER. Thank you very much, and thank you very much to our very knowledgeable panel. Before I ask you some questions, let me predicate this on the fact that all of us on this side of the room are faced with a huge challenge, and that challenge is for the last three years our country has spent \$5 trillion more than we have taken in and that if we do not stop that, if we do not have some way to pull that back so we are no longer going into debt at

such a high rate, our economy will collapse, the currency will collapse, the system will collapse. So I am predicating my comments

on that before we get into the questions.

Now, with that understanding, how we are going to get out of that depends on about what you are talking about. We have got to make sure that we develop the technology that we are capable of in this country, not only just develop it but put it in place and see that it is working, commercialize it so that it is developing, it is permitting us to do the things we need to in a cheaper and better and faster way that only new technology will permit us. In other words, \$5 trillion in debt, we have got to produce the equivalent of \$5 trillion worth of labor or focus and activity or wealth in our

society.

With that said, there are several different approaches. Some of the approaches we have heard today, like we just heard a litany of, are focused on very specific—say we have got to pick the low-hanging fruit, got to find those technologies that have the best chance of making it and making a contribution. Unfortunately, we have a focused approach, and you are relying on the bureaucracy or on government to do this, to select who is the low-hanging fruit. What happens is you end up with cronyism, and in the midst of that \$5 trillion debt, a close examination of that will show that a substantial amount of money, hundreds of billions of dollars, are ending up in the pockets of cronies. Decisions that were made, "Oh, yes, you have got a good project because you are my buddy." And we end up building factories in Finland, for example, with the stimulus package, or we end up just in time giving a solar energy company \$250 million just before they go out of business.

So what I would like to look at are the general policies which I believe is if you have a general field of policies in place, you look at those policies and find out what can make sure that an overall environment for the development of new technology is put into

place, rather than relying on focused programs.

So I am going to ask you about those general policies. We have a general policy that is represented by the FDA. We have a general policy that we are going to protect the public from people who are offering things that have not been thoroughly examined that might be harmful to them. Are we now protecting our people to death? Is the FDA—I know three or four examples myself of drugs and changes and innovations that the FDA has to approve that they have been sitting on because they are a bureaucracy. Do we need major FDA reform or some kind of restructuring or at least some sort of systematic attempt to make the FDA more efficient? Go right ahead, Dr. Cohen.

Dr. Cohen. Thank you, Congressman. As I indicated earlier, I do believe that the system that we have in place now has many virtues, but it has become overly, if I may use the word, bureaucratic and too slow and too complex. And it needs to be streamlined. It needs to be put in a position where it can expedite develop-

ment----

Mr. ROHRABACHER. Well, aren't we spending billions of dollars now that in the end, once something is approved, we figure out those billions of dollars were actually not necessary and perhaps time that we could be serving people who are suffering with a new

technology, that now they won't be able to utilize this new technology or a new medicine? As I say, that is a cost. We are talking about wasting huge amounts of money.

Dr. COHEN. You are speaking about the billions of dollars that

are spent on FDA?

Mr. ROHRABACHER. FDA approval, for example.

Dr. Cohen. Yeah. It is a question that is beyond my ability to answer because I think you are asking a societal question, and at the end of the day, society, and in particular the patients who are affected and their loved ones, need to come to consensus over time over what risk-benefit ratio they are willing to accept. Because, clearly, I think we all agree that there needs to be regulation to protect the public and ensure that what my industry is putting out there is, in fact, at some minimal level of safety and effectiveness that we all want and accept.

Having said that, so I believe we need a strong FDA. I do believe we need to invest in the FDA because it helps all of us. It helps

me to develop the right kind of medicines.

Mr. ROHRABACHER. We need an FDA that functions. We need a patent system so that—

Dr. COHEN. Correct.

Mr. ROHRABACHER [continuing]. People who are inventing new technologies will be protected and a copyright system and people who are coming up with new medicines and new technologies—let me ask one question, just informationally here. The President's health care plan, I am not sure about this detail. I heard that there was a new tax on health technology in the new bill. Is that right? There is not? I am asking you. I am not sure.

Mr. Bendis. I am not positive of that, but I think there has been

some confusion related to that issue.

Mr. Rohrabacher. Yeah, because I saw a list of things that people are saying that would need to be fixed in the bill, and one was that we are actually discouraging health care technology because we are taxing new health care technology by two percent or something. If we are doing that, that is insane because if you have new health care technology, you might be saving more than that.

Thank you, Madam Chairman.

Mrs. BIGGERT. Gentleman's time has expired. I would like to thank all the witnesses for their valuable testimony. You have been a great panel. And I would like to thank the Members for their questions, and the Members of the Subcommittee may have additional questions for the witnesses, and we would ask you to respond in writing. And the record will remain open for two weeks for additional comments and statements from Members.

With that, the witnesses are excused, and thank you all for com-

ing, and this hearing is now adjourned.

[Whereupon, at 11:30 a.m., the Subcommittee was adjourned.]

Answers to Post-Hearing Questions

Answers to Post-Hearing Questions

Responses by Mr. Ron Cohen

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QUESTIONS FOR THE RECORD THE HONORABLE BEN QUALYE (R-AZ) U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

1. What do you believe is more important for policy makers to focus on—targeted policies designed to provide an immediate boost to the economy or economic policies designed to create the conditions for long-term growth?

Both short- and long-term policies are critically important to the success of the biotech industry and the health of the United States' 21st century innovation economy. For example, the Therapeutic Discovery Project (TDP) injected \$1 billion of immediate capital into the industry in 2010, creating American jobs and driving the innovative search for cures and treatments. The awards provided critical, timely funding to biotech researchers on the cusp of scientific breakthroughs. However, Congress must follow-up on this successful program with long-term policies that will provide a more hospitable environment in the U.S. for innovative companies that will drive America's economic growth.

2. In your testimony, you state that the FDA needs to be more clear and consistent in its application of standards and its communications with drug developers. Can you give us a sense of how this lack of clarity and consistency affects your company and others in your industry? What do you believe are the long-term effect on innovation in this country from lack of clarity and consistency in regulations?

FDA's approval processes for new drugs and biologics profoundly impact the discovery and development of new treatments for diseases, to a degree that is difficult to overstate. There is no question that protecting patients from harm is a critical component of FDA's mission. But so too is enabling the timely development and availability of effective new therapies for patients suffering from serious and life-threatening diseases. In a time when the U.S. medical innovation ecosystem is facing severe strains and increased global competition, it is imperative that FDA's policies and practices find the right balance between these objectives to ensure we are able to deliver the next generation of breakthrough treatments and therapies.

Too often, development is hampered by inefficient, opaque FDA processes and poor or untimely communications, which culmulatively can add years and tens of millions of dollars to development costs. My own company experienced these issues first-hand during the approximately 15 years it took us to develop our MS drug through FDA approval in 2010. To be clear, we found FDA's staff overall to be dedicated professionals who want to do the best job possible. But they were often challenged by chronic understaffing and what appeared to be overly bureaucratic process.

From 1999-2005, the average duration of clinical trials in the U.S. grew by $70\%^l$ and, since 2001, the average time to achieve approval of new drugs has increased from 12.4 to 14.8 years.2

¹ Tufts Center for the Study of Drug Development, 2008. "Growing Protocol Design Complexity Stresses Investigators, Volunteers." Impact Report. 10.1

² Source: CMR 2011 Pharmaceutical R&D Fact Book, Thomson Reuters.

For patients and their families, such delays are unfair and should not be acceptable. For small biotech companies that have become the leading engine for medical breakthroughs, such delays are not merely costly but can be--and have been--fatal, as investors are hard pressed to continue to fund development programs.

At the same time, patient groups have comparatively little say in the drug approval process. Yet in the end, it is they who must make the ultimate risk-benefit decisions that affect their lives. It would be useful if, as part of the approval process, the FDA were required not only to quantify the risk of putting a potentially unsafe drug on the market, as it does now, but also to quantify the risk of delaying availability of a potentially effective therapy to patients who need it.

While America has developed more cures and breakthrough medicines than any other country and is home to over 2,500 biotech companies, our global competition is increasing at an unprecedented rate, as rapidly rising economic powers such as China and India are committing billions of dollars to develop their own life sciences industries. Our leadership position will not be sustained without a concerted policy focus on supporting and incentivizing the next frontier of biomedical discoveries, treatments, and cures. A critical component of these policies needs to be a modern FDA and a regulatory environment that is consistent and clear to patients, doctors, and industry.

Although there have recently been a few headlines touting increased investment in the biomedical field, these headlines oversimplify the actual state of affairs. The National Venture Capital Association (NVCA) recently released their fourth quarter 2011 numbers for venture financing in biotechnology in the U.S. While the numbers showed an overall 18% increase in investment from 2010 to 2011, this is not reflective of the situation that most small, innovative biotechnology companies are facing. Investment in biotechnology in 2011 was 12% lower than the peak we saw in 2007. Additionally, first round venture deals in 2011 fell below 100 for the third time in a decade and the total number of venture financing deals is down 8% since 2010. Most importantly, especially to small innovative companies, the number of venture-funded early-stage companies fell 19%. The number and quantity of investments moving away from early-stage innovative projects is a very disturbing trend that has been growing over the past few years, and this in large part directly reflects investor avoidance of the increasing risks of the regulatory process. In fact the number of first-time financing for life sciences companies is at its lowest level since 1996.

The October 2011 survey conducted by the NVCA and MedIC showed that 40% of venture capitalists expect to decrease investment in biopharma over the next three years, three times as many as the number who expect to increase. Indeed, during the past year several long-time investment funds announced that they will no longer be investing in the medical science sectors. This same survey showed that 61% cited regulatory challenges at the FDA as the main reason for reducing investments.

While it is undeniably important to assure the safety of new drugs coming to market, it is equally important to recognize the benefits of new therapies. It is also essential to recognize that the way

in which these objectives are balanced has enormous implications for our country's ability to maintain leadership in turning science into breakthrough products. We must have an FDA that is empowered and enabled to consistently and expeditiously review innovative products; otherwise, the risk of investment in medical innovation will continue to increase, driving investment capital away from U.S. life sciences and into other industries and other countries. To this end, I believe that the FAST Act currently being considered in the House, and the analogous TREAT bill in the Senate, go a long way toward improving our current regulatory system, and should be enacted.

3. In your testimony, you recommend changing the definition of "qualified small businesses" under Section 1202 to include companies with gross assets up to \$150 million, to index the cap to inflation, and to exclude intellectual property and follow-on rounds of financing from the gross assets test. Can you elaborate on what makes capital-intensive industries different, and on how reforms to these rules would improve competitiveness? Also, you suggest that the definition of "ownership change" should be expanded to allow companies that have undergone an ownership changes as a result of certain investments, like venture financing, to still use net operating losses. What types of investments should this expanded definitions of ownership change include? What possible risks are there to expanding this definition?

It takes 10 to 15 years for a company to bring a new medicine from discovery, through clinical trials, and on to FDA approval of a product. The entire endeavor costs on average between \$800 million and \$1.2 billion. I personally had to raise \$600 million over a 15 year period in order to bring Acorda's first drug to market, a breakthrough therapy that improves the ability of MS patients to walk. This capital-intensive process is most often undertaken by companies with virtually zero product revenue, so all research and development funds must come from investors. The significant capital requirements necessitate fundraising through a wide range of investors, and growing biotech companies need investors who are willing to support this long, high risk, expensive development process.

Congress' original intent in enacting Section 1202 was to encourage and reward individuals for taking risks by investing in new ventures and small businesses. However, by limiting the exclusions for qualified small business stock to investors in companies with less than \$50 million in gross assets, the current Section 1202 does not provide adequate incentives to invest in small companies. The capital-intensive nature of R&D companies like those in the biotech industry pushes them above \$50 million in gross assets and disqualifies them and their investors from the benefits of Section 1202.

By making changes to the requirements in Section 1202, including raising the gross assets ceiling to \$150 million, Congress can stimulate investment in growing innovative companies. These companies should not be penalized for their valuable IP and successive rounds of follow-on financing – these are important indicators of a biotechnology company's health and attractiveness for future investment; by exempting these from the gross assets test, Congress can incentivize investment in small companies rather than restricting it. At a time when other countries are aggressively funding their own biotech industries in an effort to bolster their own competitiveness and attract American companies, incentivizing domestic investment in biotech should be a key component of Congress's innovation agenda.

Similarly, Section 382 was enacted with commendable intent – to curtail NOL trafficking. However, small biotech companies are caught in its scope because their reliance on multiple rounds of financing triggers the ownership change restriction. I believe that investments in start-up companies in a loss position with fewer than 500 employees and with at least 35% of expenditures going toward research and development should not qualify as an ownership change and, therefore, that those companies should be able to retain their NOLs. These investments in innovative companies are not what Congress was targeting when it restricted ownership changes – because of these small companies' lack of revenue, any new investment is technically a loss-restricting ownership change, despite the fact that they operate at a loss for more than a decade. If small biotech companies could retain their NOLs, they would be able to include them as tax attributes on the balance sheet, thus increasing their value when preparing for additional rounds of financing like mergers or initial public offerings. This change would incentivize investment in biotech and drive innovation.

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QUESTIONS FOR THE RECORD THE HONORABLE RANDY NEUGEBAUER (R-TX) U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

1. The U.S. federal debt is now approaching \$16 trillion, with no end in sight. How do our fiscal problems figure into your long-term business decisions and outlook?

Certainty and predictability are extremely important for growing companies making long-term business decisions. Stable funding for important agencies like NIH and predictability from Congress on coverage, funding, and broader fiscal issues will enable companies and their investors to look down the road and make long-term decisions that will promote economic growth, which in turn will contribute importantly to reduction of the overall U.S. debt.

2. I regularly hear from small businesses that federal regulation results in massive commitments of human capital, time, and resources to completing paperwork and ensuring compliance. If you have experienced this issue, please provide examples. How does this affect your business operations? What can Congress do to alleviate this imposition?

The FDA process alone required that my company hire significant additional staff, as well as several outside consulting groups costing several million dollars each. Our New Drug Application comprised over a million pages, which we had to convert to digital format and in which we had manually to insert thousands of hyperlinks. To prepare for the Advisory Committee meeting called by FDA required us to create over 1,200 slides and to devote over 5 months of preparation, which consumed a large percentage of the time of our scientific and clinical staff, time that otherwise could have been devoted to our other drug development programs.

In a similar vein, Sarbanes-Oxley compliance required that our very small company of fewer than 80 at the time of our IPO in 2006, spend over \$2 million of our scarce dollars and hire additional staff specifically for this purpose. Congress recently took an important step toward alleviating regulatory burdens by passing the Jumpstart Our Business Startups (JOBS) Act. This legislation will provide emerging growth companies five years to find their feet on the public market before having to comply with burdensome regulations like Sarbanes-Oxley (SOX) Section 404(b) and certain other accounting and disclosure requirements. The exemption from SOX Section 404(b) will allow growing companies time to focus on their innovative research before having to divert funds to costly regulations. The JOBS Act will also ease private fundraising through an expansion of the eligibility requirements for SEC Regulation A offerings and broaden the investor base by reforming the SEC private shareholder limit and SEC Regulation D.

The new law will ease capital formation for growing biotechnology companies, giving them access to both private and public investors at a time in their growth cycle when they have little to no product revenue to offset the costs of conducting groundbreaking research. Currently, venture financing is stagnant and the public market remains closed to many biotech companies.

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By removing regulatory burdens, the JOBS Act will allow companies to focus on the search for cures and breakthrough medicines rather than bureaucratic red tape.

Responses by Mr. Mick Truitt

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OF Scientific and Industrial Instruments

April 12, 2012

The Honorable Ben Quayle Chairman, Subcommittee on Technology and Innovation Committee on Science, Space, and Technology 2321 Rayburn House Office Building Washington, DC 20515

Dear Chairman Quayle:

I would like to thank you and the entire committee for allowing me to appear before you and for listening to the issues and concerns facing Ludlum Measurements Inc.. I especially wanted to stress how the issues of immigration and taxes affect all companies no matter what their size or where they are located in the United States. Hearings such as this are essential for our congressional leaders to hear directly from businesses and understand how regulations and policies they are making impact the people they govern. Attached please find the responses to the questions submitted to me. Please feel free to call upon me anytime when I may be of service.

Thank you again for the opportunity to express my views and concerns,

Mick Truitt

Ludlum Measurements Incorporated

Vice President of Sales, Marketing and Business Development

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QUESTIONS FOR THE RECORD THE HONORABLE BEN QUALYE (R-AZ) U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth.

Tuesday, March 27, 2012

Responses by Mick Truitt, Vice President of Ludlum Measurements, Inc. and may or may not reflect the views of the U.S. Chamber of Commerce.

- 1. What do you believe is more important for policy makers to focus on—targeted policies designed to provide an immediate boost to the economy or economic policies designed to create the conditions for long-term growth?
 - Response When it comes to questions of policy in this issue area, Congress should operate like a business. It is always a balance. You need some short-term projects/policies for cash flow and immediate growth and long-term projects/policies to make sure you have a secure foundation for the future. What is important to always remember is that the United States economy is like a company in that it is either growing or dying. Congress should focus on putting in place policies that foster an environment that encourages businesses and entrepreneurs to invest, expand and create jobs which will in turn get our economy moving in the right direction.
- 2. In your testimony, you stated that LMI is structured for tax purposes as a Subchapter S corporation and that company profits are passed through to shareholders and taxed at the individual's marginal income tax rate. Could you elaborate on what the implications would be for your business if marginal individual income tax rates were to increase at the end of this year? In your experience would this affect other emerging innovative companies?

Response - The increase in the marginal tax rate for the individual would have huge and harmful implications for our business. Ludlum Measurements Incorporated (LMI), like other Sub Chapter S corporations, pays distributions to cover individual shareholder taxes. Therefore, if individual tax rates are allowed to increase, distributions would be higher leaving less cash in the corporation to reinvest. LMI has a policy of reinvesting all funds possible back into the company through capital equipment purchases and hiring employees. If there was less cash available because the individual rates are permitted to increase, LMI would not be able to hire as many employees or buy more equipment. New and emerging companies would be hit even harder. They have less cash to begin with and the more funds that go to the government due to higher taxes, then they have less to reinvest and keep the company afloat.

QUESTIONS FOR THE RECORD

THE HONORABLE RANDY NEUGEBAUER (R-TX)

U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

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Tuesday, March 27, 2012

Responses by Mick Truitt, Vice President of Ludlum Measurements, Inc. and may or may not reflect the views of the U.S. Chamber of Commerce.

1. The U.S. federal debt is now approaching \$16 trillion, with no end in sight. How do our fiscal problems figure into your long-term business decisions and outlook?

Response – We are an international company in that we sell and ship goods all over the world, but we also own a company in England. We deal in various currencies in our business. When the United States federal government cannot pay its own bills it drastically hurts our economy which in turn hurts our business. When the dollar is weaker, it costs us a lot more money through currency exchange. The Unites States of America certainly has the means to cover its own debt, and I'm extremely disappointed that our leaders have let us get in this bad of financial shape. A business is not allowed to operate in this manner, why should our government?

2. I regularly hear from small businesses that federal regulation results in massive commitments of human capital, time, and resources to completing paperwork and ensuring compliance. If you have experienced this issue, please provide examples. How does this affect your business operations? What can Congress do to alleviate this imposition?

Response — There are really too many examples of this to explain in a short period of time. I will stick to the ones that were most directly related to the testimony. When it comes time for LMI to hire new highly technical people what sometimes becomes apparent is that we have to go not only outside of Texas but outside of the United States to get the expertise we require. In the one example of the person we hired from Mexico it has cost LMI over \$17,000 and probably 1,000 hours to go through the appropriate channels and paperwork to get this accomplished. It would be very beneficial to LMI and companies in a similar situation to alleviate this unnecessarily burdensome process to allow us to acquire the high level personnel with advanced degrees we need. We should be able to be expedite this process with user friendly forms and less onerous paperwork so that it does not take special legal help to maneuver through what is currently a very cumbersome process.

Another issue is the R&D tax credit. The paperwork required to be documented is significant and can actually cut into the time an engineer has available to design new products. LMI is hesitant to spend this much engineering time on the paperwork that is required to take full advantage of this tax credit. This hesitation is exacerbated due to the reality that every year we are unsure whether the credit is going to again be extended or not. Making the R&D tax credit permanent would alleviate these concerns, give us a long-term solution and empower LMI to invest the time and resources required to take full advantage of the R&D tax credit.

QUESTIONS FOR THE RECORD THE HONORABLE DANA ROHRABACHER (R-CA)

U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

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Tuesday, March 27, 2012

Responses by Mick Truitt, Vice President of Ludlum Measurements, Inc. and may or may not reflect the views of the U.S. Chamber of Commerce.

- What impact will the 2.3 % tax on medical devices have on innovation, job creation, and U.S. global competitiveness?
 - Response LMI has to consider any new tax as an additional cost which has to be offset by the price of the instrument. When calculating this cost, it is not only the 2.3% for the tax but in this case an additional 0.5% for the overhead to track and file these taxes. This additional approximately 3% is nothing but overhead and adds no intrinsic value to the instrument that can be used to show how LMI products compare to other products made outside the United States that do not have this kind of tax.
- 2. Will the medical device industry and small manufacturers pass this tax on to consumers in higher prices for patient care?
 - Response LMI would have to pass this additional tax and overhead onto our customers, who in turn set the prices for patient care. While we cannot speak directly for them, I do not see how they would be able to be in business without passing additional costs onto their customers who are their patients.
- 3. Are we stifling innovation with unnecessary tax burdens on small businesses who are trying to promote economic growth?
 - Any taxes and overhead tie up and redirect time and money that cannot then be used to add new equipment or employees. Also any new regulations tie up employee time just reviewing and determining if and how the new regulation affects LMI.

Responses by Mr. Thomas M. Brandt, Jr.

QUESTIONS FOR THE RECORD THE HONORABLE BEN QUALYE (R-AZ)

1. What do you believe is more important for policy makers to focus on—targeted policies designed to provide an immediate boost to the economy or economic policies designed to create the conditions for long-term growth?

With respect to policies to boost the economy and economic growth, I believe there is a place for both short-term and long-term policies that can work together. As the economy is still turning around, targeted policies can provide companies, especially smaller ones, with the tools they need to keep employment steady, increase employment, invest in R&D, and continue to grow their businesses. That said, I believe economic policies focused on long-term growth are extremely important and should always be part of the discussion. Long-term policies will provide innovators with the certainty and predictability they need when making long-term planning decisions.

In addition, foreign governments, are increasingly aggressive in promoting favorable tax policies, improving their legal, accounting and intellectual property structures, and boosting their R&D spending to foster innovation in their countries. The U.S. needs to meet the challenge of foreign competitors or risk losing our technological edge. To maintain our nation's competitive advantage, we must update public policy to support what has made us successful: Improving access to capital with smart tax policies, increasing support for basic R&D, improving math and science education, supporting immigration and opening new markets.

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QUESTIONS FOR THE RECORD THE HONORABLE RANDY NEUGEBAUER (R-TX)

1. The U.S. federal debt is now approaching \$16 trillion, with no end in sight. How do our fiscal problems figure into your long-term business decisions and outlook?

As a small / midcap technology company, TCS is affected by access to and cost of capital. To the extent that interest rates in general are affected by market uncertainty about the US treasury's ability to fund deficits, we are impacted. Our company is also a vendor of technology to US government agencies, and uncertainties about budgets and funding also adversely affect the willingness of investors to support our company.

2. I regularly hear from small businesses that federal regulation results in massive commitments of human capital, time, and resources to completing paperwork and ensuring compliance. If you have experienced this issue, please provide examples. How does this affect your business operations? What can Congress do to alleviate this imposition?

Accessing public equity markets to fund our business has become increasingly expensive since our IPO in 2000, mainly due to audit and staff fees to comply with SEC requirements including Sarbanes Oxley requirements. In 2010-11, our annual audit and related fees have been in the \$800-\$900,000 range, while the market value of the securities protected by these regulations has been in the \$100-\$250 million range. So it is clear that the proportion of financial market policing cost to economic risk has been extraordinarily high for us.

Entrepreneurial, smaller businesses like ours have been the victims of the broad brush of "regulation" falling disproportionately on small and large risks. By definition, investors in smaller companies are doing so on the fundamentals of the business plans, markets, and technology. High profile cases large-loss cases have tended to involve large scale complex derivative securities and deal structures.

In terms of what Congress can do to address this, passage of the JOBS Act was a step in the right direction in terms of creating an "on-ramp" for companies going public. The Startup Act, introduced by Senators Warner and Moran, is another piece of legislation that would address the disproportionate impact of regulations on smaller companies. The bill would require a cost-benefit analysis of proposed regulations with an impact of \$100 million or more to determine its potential impact on the formation and growth of new businesses. By better studying and reviewing proposed laws and regulations before they go into effect, we may be able to avoid some of the extraordinary implementation problems that resulted after enactment of the Sarbanes-Oxley Act.

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QUESTIONS FOR THE RECORD THE HONORABLE BEN QUALYE (R-AZ) U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth.

Tuesday, March 27, 2012

1. What do you believe is more important for policy makers to focus on—targeted policies designed to provide an immediate boost to the economy or economic policies designed to create the conditions for long-term growth?

I BELIEVE BOTH ARE IMPORTANT AND WE SHOULD NOT MAKE AN EITHER OR DECISION. WE SHOULD TAKE A BALANCED PORTFOLIO APPROACH LOOKING ALL THE WAY BACK TO PROOF OF CONCEPT OPPORTUNITIES AS WELL AS MATURE INDUSTRIES, SUCH AS MANUFACTURING AND DEVELOP POLICY THAT WILL HELP BOTH THE SHORT TERM IN CREATION OF MORE HIGH SKILLED OPERMANENT JOBS AND LONG TERM BY PROTECTING EXISTING JOBS THAT MIGHT HAVE GONE OVERSEAS BUT ARE STARTING TO COME BACK TO THE U.S.AS WELL AS PROTECT OTHER CRITICAL JOBS THAT WE MIGHT LOSE OVERSEAS.

QUESTIONS FOR THE RECORD THE HONORABLE DONNA EDWARDS (D-MD) U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

Fostering the U.S. Competitive Edge: Examining the Effect of Federal Policies on Competition, Innovation, and Job Growth.

Tuesday, March 27, 2012

1. You note that the Office of Innovation and Entrepreneurship and the National Advisory Committee on Innovation and Entrepreneurship should have greater visibility within the Administration and Congress in order to effectively serve as the central location and focal point of Federal innovation activities, as well as foster interagency cooperation in this area. Can you tell us what you think needs to be done to strengthen the Office and have it realize its full potential, as envisioned in the America COMPETES Reauthorization Act of 2010?

THE OFFICE NEEDS AT LEAST AN ASSISTANT SECRETARY IF NOT FULL SECRETARY CLASSIFICATION. THE CURRENT POSITION OF OIE IS LOST WITHIN DOC/EDA DOES NOT HAVE A BUDGET OR STAFF AND ALSO DOES NOT HAVE A CLEAR MISSION THAT CAN BE MEASURED. IT MAY BE MORE APPROPRIATE TO CREATE A NEW PRIVATE/PUBLIC PARTNERSHIP OUTSIDE OF GOVERNMNET LED BY THE PRIVATE SECTOR WHERE GOVERNMENT IS A PARTNER BUT SUPPORTS AND DOES NOT CONTROL AN OFFICE OF INNOVATION AND ENTREPRENERSHIP WHICH ARE BASICALLY DRIVEN BY PRIVATE SECTOR AND ENTREPRENEURS. THE U.S. DOES NOT HAVE A LONG TERM, SUSTAINABLEAND INTEGRATED INNNOVATION AND ENTREPRENEURSHIP STRATEGY OR IMPLEMENTATION PLAN AND THIS ENTITY SHOULD BE RESPONSIBLE FOR DEVELOPING AND MONITORING ITS EFFECTIVENESS

2. In your testimony, you mention the need for the Economic Development Administration to have "additional flexibility in program design and implementation" in relation to its Regional Innovation Program because "every region in the U.S. has their unique assets, strengthens, and needs." Can you please elaborate on the current constraints that EDA is operating under with respect to their Regional Innovation Program and why this is a concern?

THE EDA PRIMARILY FOCUSES ON ECONOMICALLY DISTRESSED COMMUNITIES AND REGIONS IN THE U.S. IT SHOULD HAVE THE FLEXIBILITY TO HAVE STRONG AND WAK REGIONS WORK TOGETHER TO FORM STRONGER REGIONAL INNOVATION CLUSTERS AND THE EDA ALSO IS SEVERELY LIMITED BY THE SIZ E OF ITS ANNUAL BUDGET. THE EDA IS THE MOST ENTREPRENEURIAL FEDERAL AGENCY AS THE NEW 16 COMPETITIONS DEMONSTRATES BUT AWARDING 6 \$1 MILLION AWARDS WILL NOT HAVE A SIGNIFICANT IMPACT UNLESS LARGER AND MORE AWARDS ARE MADE. EDA IS LOOKED UPON AS A SECOND CLASS

AGENCY SINCE ITS BUDGET IS SO SMALL IN COMPARISON TO THE MAJORS , BUT ITS CURRENT AND POTENTIAL IMPACT ON AMERICA CAN BE GREAT

QUESTIONS FOR THE RECORD THE HONORABLE RANDY NEUGEBAUER (R-TX) U.S. House Committee on Science, Space, and Technology Subcommittee on Technology and Innovation

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Tuesday, March 27, 2012

1. The U.S. federal debt is now approaching \$16 trillion, with no end in sight. How do our fiscal problems figure into your long-term business decisions and outlook?

THE U.S. FISCAL PROBLEMS HAVE A NEGATIVE IMPACT ON EVERYONE INCLUDING, THE STATES, CITIES, INDUSTRY, ACADEMIA AND ENTREPRENEURS. ENTREPRENEURS AND INNOVATORS HAVE TO FIND WAYS TO BOOTSTRAP THEIR OPERATIONS TO TRY TO GET NEW PRODUCTS AND SERVICES TO THE MARKET AND UNFORTUNATELY GOVERNMENT AT ALL LEVELS DOES NOT HAVE THE NECESSARY TOOLS AND PROGRAMS TO ASSIST THEM.

I BELIEVE THERE NEEDS TO BE A CRITICAL ANALYSIS OF THE EXISTING FEDERAL PORTFOLIO OF PROGRAMS AND DETERMINE IF ALL ARE WORTHY OF FUNDING IN TODAY'S ENVIRONMENT. UNTIL A STRATEGIC PLAN FOR INNOVATION AND ENTREPRENEURSHIP IS DEVELOPED IT IS HARD TO DETERMINE WHERE THE GAPS ARE THAT GOVERNMENT NEEDS TO ADDRESS AND WHERE THERE MAY BE ANTIQUATED POLICIES OR PROGRAMS THAT WE DON'T NEED.

I BELIEVE THERE IS MORE THAN ENOUGH MONEY TO GROW OUR ECONOMY IN THE BUDGET, BUT WE ARE AFRAID TO MAKE THE DIFFICULT DECISIONS TO CUT PROGRAMS OR REPURPOSE BUDGETS TO WHERE THERE ARE GREATED NEEDS TODAY FOR THE FUTURE.WE NEED TO ELIMINATE SOME LEGACY AND PORK PROGRAMS TO RIGHT SIZE OR BUDGET.

2. I regularly hear from small businesses that federal regulation results in massive commitments of human capital, time, and resources to completing paperwork and ensuring compliance. If you have experienced this issue, please provide examples. How does this affect your business operations? What can Congress do to alleviate this imposition?

THERE ARE UNNECESSARY DELAYS IN THE DECISION PROCESS FOR GOVERNMENT PROGRAMS ESPECIALLY THOSE THAT EFFECT SMALL BUSINESS AND ENTREPRENEURS. A PRIME EXAMPLE IS THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM (SBIR), WHERE IT TAKES SEVERAL MONTHS AFTER AN APPLICATION IS MADE TO MAKE DECISIONS

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ON AWARDS. IN ORDER FOR AMERICA TO REMAIN GLOBALLY COMPETITIVE WE NEED TO BE DECISIVE IN MAKING DECISIONS IN CRITICAL NEW EMERGING INDUSTRIES AND TECHNOLOGY AREAS WHERE FOREIGN COMPETITION IS BECOMING MORE FORMIDABLE. THE U.S. GOVERNEMNT NEEDS TO BECOME MORE ENTREPRENEURIAL IN ITS, DECISION MAKING, PROGRAMS AND POLICIES SO AS TO BE ABLE TO COMPETE MORE EFFECTIVELY IN THE GLOBAL INNOVATION ECONOMY.

Appendix 2

ADDITIONAL MATERIAL FOR THE RECORD

TECHAMERICA: TECHNOLOGY ROADMAP FOR AMERICA

TechAmerica

Technology Roadmap for America

To remain competitive in today's world - and to find solutions to our most pressing needs - our nation must transform itself and create an innovation economy. In the 21st century, our health, education, economy, national and homeland security and global competitiveness are all dependent on innovation technology and policies. Preparing Americans to create and perform jobs of the future requires investment in the "building blocks" of innovation. We urge Congress to enact a Technology Roadmap:

- Research and Development. Strengthen and make permanent the R&D tax credit. The current credit's on-again, off-again nature impedes long term research planning by industry.
- Trade. Implement an innovation-based national trade policy with new free trade agreements that
 open up new markets and expand existing ones for U.S. firms to export products.
- Jobs, Education and Training. Ensure a competitive 21st century workforce through a greater emphasis on science, technology, engineering and math education and initiatives to strengthen life-long learning opportunities.
- 4. Intellectual Property. Enact meaningful patent and content protection to drive innovation.
- Cybersecurity. Protect our nation's technology infrastructure and ensure citizens are shielded from cyber attack, data breaches and hackers. Promote trusted identifies online.
- Privacy. Promote consumer trust and confidence in online commerce. Provide consumers with reasonable choice and control while allowing for technological innovation that spurs innovation.
- Broadband. Meet our broadband challenge through innovative solutions that accelerate broadband deployment and adoption. Adopt spectrum and Universal Service Fund reforms.
- Government Management. Improve government effectiveness with adaptation of innovative technologies, OMB IT plan implementation, and repeal of contractor withholding.
- National Security and Homeland Security. Technology deployment is a critical element to success in these missions and also drives innovation in the private sector.
- 10. Immigration. Strengthen our economy by fixing America's broken skilled immigration system.
- 11. Competitive Tax Code. Enact pro-innovation tax reform and a temporary repatriation incentive.
- 12. Cloud. Implement a framework that promotes public and commercial sector cloud computing.
- Smart and Clean Energy. Promote technology solutions as a means to solve the nation's energy challenges.

For more information, contact TechAmerica SVP for Federal Government Affairs Kevin Richards at kevin.richards@techamerica.org or 202.595.3062.

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